Cedex Bio HT

Operator's Manual

Version 1.2

Revision history

Manual version	Software version	Revision date	Changes
1.0	5.0	May 2012	First release
1.0	5.0	September 2012	Updated laser information
1.1	5.0	April 2013	Remote access, diluent handling, 2nd LAN connector
1.2	5.0	September 2013	Hardware specifications, data handling via USB

Publication notice

This publication is for users of the *Cedex Bio HT* analyzer.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, Roche reserves the right to make any changes necessary without notice as part of ongoing product developments and improvements.

Any customer modification to the instrument will render the warranty or service agreement null and void.

Intended use

The *Cedex Bio HT* analyzer is a fully automated, computerized analyzer for professional use. It is intended for determination of a wide range of analytes in various aqueous solutions like cell culture and fermentation media.

For use in quality control/manufacturing process only.

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Instrument approvals

The *Cedex Bio HT* analyzer meets the protection requirements laid down in:

- Council Directive 2004/108/EC on the alignment of the legal provisions of the Member States on electromagnetic compatibility (EMC).
- Council Directive 2006/95/EC on the alignment of the legal provisions of the Member States on electrical equipment for use within certain voltage limits.

Compliance is provided by means of the Declaration of Conformity.

Regulatory compliance is demonstrated by the following marks:

CE	Complies with European Union (EU) Directives 2004/108/EC and 2006/95/EC.
c UL® US	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Contact address

🏭

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Made in Switzerland

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Revisions

Preface

This manual refers specifically to the *Cedex Bio HT* analyzer and software version 5.0.

About the Cedex Bio HT analyzer

The *Cedex Bio HT* analyzer is an advanced integrated system for monitoring of substrates and metabolites for process control of cell culturing and fermentation.

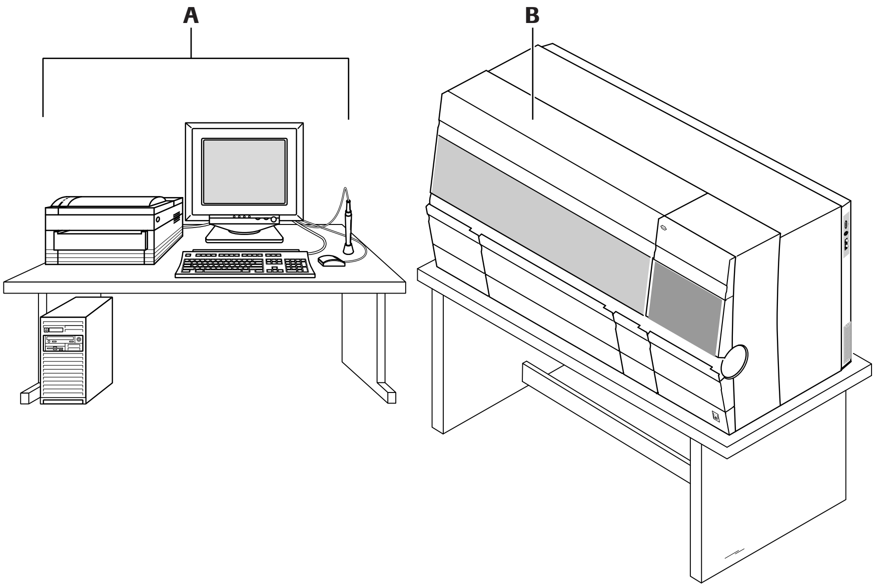
Testing of electrolytes, carbohydrates, amino acids, specific proteins and enzyme activities is consolidated into one system with a convenient reagent cassette design.

Robust robotics, an intuitive user interface and random sample access serve for optimized time management and streamlined workflows.

The ISE (Ion Selective Electrode) module allows the determination of sodium and potassium in parallel with absorbance- and FP photometric measurements.

Reagent cassettes, calibrators, controls, and samples are identified by a barcode scanner.

The high performance, flexibility, and versatility of the *Cedex Bio HT* analyzer make this system suitable as a routine analyzer as well as a dedicated instrument for specific tasks.



A *Data station*

B *Instrument*

How to use this manual

This manual is designed to help you perform all of the tasks that are required as part of your work with the *Cedex Bio HT* analyzer.

If you are a new user, the manual will also help you to understand general hardware principles, the user interface, the status of the instrument and its modules. You should familiarize yourself with these areas before attempting to perform daily tasks.

You can also find information about how to use the *Cedex Bio HT* analyzer in the *Online Help*.

Content

The manual is divided into the following parts:

- Part A - Overview: Contains general information about the *Cedex Bio HT* analyzer, about the basic concepts of using the instrument, the hardware, the software, and the online Help.
- Part B - Operation: Starts with a workflow description for some typical laboratory setups, using step-by-step instructions. It then describes how to perform all the day-to-day tasks necessary to create orders, monitor the status of the instrument, view results, and deal with some simple problems that do not require detailed analysis.
- Part C - Flags: Describes the flags that are generated for unaccepted results and gives recommended actions.
- Part D - Service: Describes how to start and perform service actions that are essential to maintain maximum productivity from this instrument.
- Part E - Troubleshooting: Describes how to pinpoint potential problems and how to solve them.
- Part F - ISE measurements: Describes the principles of operation of the ISE module and contains specialized sections on ISE flags and troubleshooting, and ISE service actions.
- Part G - Configuration: Describes some of the most common configuration tasks for a fully operational system. Full details on all configuration procedures are given in the online Help.
- Appendix: Contains additional information including a technical specification of the instrument.
- Glossary and index: Provides reference and look-up material.

Conventions used in the *Cedex Bio HT* documentation

This section describes the conventions used in this manual, including symbols, user-interface conventions, and units.

Symbols

The following symbols are used:

Symbol	Used for
►	Step-by-step procedure
👁	Cross reference
☐	Checklist
💡	Notes

User interface conventions

The following conventions are used throughout the user documentation:

User action	Meaning
Configuration / Tests / ID	**1** Click Configuration in the navigation bar. **2** Double-click Tests in the Definitions group. **3** Click the ID tab.
Choose File > Print Report > BOD Report	**1** Click File in the menu bar. **2** Select Print Report from the menu. **3** Select BOD Report from the next menu.
Shift + F3	Press the Shift key and hold it down; press and release the F3 function key; then release the Shift key.
Click	Press the left button on the mouse or the equivalent button on the system keyboard.
Click OK	Move the cursor to the OK button, and then press the left mouse button.
Click Status	Click the Status button on the navigation bar.
Click Print	Click the Print button in the current window or dialog box.
Right-click	Click the right mouse button (or equivalent on the keyboard).
Press	Press a key on the keyboard.
Double-click	Click the left mouse button (or equivalent on the keyboard) twice in rapid succession.
Open	Open the window or dialog box.
Close	Close the window or dialog box.

Units

SI units (Système International d'Unités) are used throughout the manual, where appropriate. The following units are either non-SI or may be unfamiliar to some users:

Abbreviation	Unit
BTU	British thermal unit
cm	Centimeters
in	Inches
lb.	Pounds (weight)
MΩ	Mega Ohm
psi	Pounds per square inch
VA	Volt-Amperes
VAC	Volts (alternating current)
µS	Micro Siemens

Abbreviations and acronyms

The following abbreviations and acronyms are used throughout the documentation.

Abbreviation	Meaning	Usage
abs.	absorbance	abs. measurement
BOD	Begin of Day	BOD service action
CAL	calibrator	(legend on graphic)
DIL	diluent	(legend on graphic)
FP	Fluorescence Polarization	FP photometer
ID	Identification (number)	Order ID, Sample ID
in.	internal	in. water reservoir
ISE	Ion Selective Electrode	ISE module
LCD	Liquid crystal device	LCD monitor
LED	Light-emitting diode	LED status indicator
No.	number	Lot No.
STAT	immediate order	Priority samples, tests and results
TAS	Test Application Software	Roche default test, calibration, control, and diluent definitions

Safety classifications

The safety precautions and important user notes are classified according to the following description. Before you attempt to use the *Cedex Bio HT* analyzer, you must be fully familiar with the following symbols and their meanings:

⚠ **Danger**

Indicates a direct danger that, if not avoided, may result in death or serious injury.

⚠ **Warning**

Indicates a possibly hazardous situation that, if not avoided, may result in death or serious injury.

⚠ **Caution**

Indicates a possibly hazardous situation that, if not avoided, may result in slight or minor injury or may result in damage to equipment.

Safety information

Before operating the *Cedex Bio HT* analyzer, it is essential that you both read and understand the safety information listed below.

Read all Roche safety notices carefully and make sure you understand them.

⚠ **Danger**

Electrical safety
Danger of electric shock when touching power supply components. Never attempt to access any parts of the instrument other than those specifically described in the user documentation. In particular, never open or manipulate any components on the rear of the instrument.

⚠ **Danger**

Electrical safety
Before removing main cover disconnect mains plug from socket. Hazardous voltage is present on ISE power supply even if main switch is off. Danger of electric shock when touching power supply components.

☣

Biological safety
Samples analyzed with this instrument may contain potentially infectious material. Samples derived from humans, animals, tissue culture, or in vitro cultures should be handled and processed with appropriate safety precautions. Such samples may contain bacterial, fungal or viral agents. Spills should be immediately disinfected with an approved disinfectant solution to avoid contamination of laboratory personnel and equipment.

Loss of sight due to staring into laser beam

Barcode scanner contains a class 2 laser diode.
Do not stare into the laser transmitter beam as your eyesight may be severely damaged.
For position of the laser transmitters, see "Safety information for laser transmitters" on page xxi.

Danger

Danger of explosion

Danger of explosion through sparks. Keep all potentially inflammable or explosive material (for example anesthetic gas) away from the instrument.

Danger

Fire risk

Spraying liquid on the power supply parts can cause a short circuit and result in a fire. Keep the cover closed while the instrument is connected to the main power supply and do not use sprays in the vicinity of the Cedex Bio HT analyzer.
During fire-fighting operations disconnect the Cedex Bio HT analyzer from the main power supply.

Warning

Instrument in use

Danger of injury to hands by moving parts. Keep the instrument cover closed while initialization or measuring is in progress.

Warning

Malfunction of instrument and incorrect results due to interfering electromagnetic fields

Devices that emit electromagnetic waves may cause the instrument to malfunction. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

Warning

Sample

Danger of infectious sample material which can cause severe illness. Avoid direct contact with sample material. Clean contaminated surfaces immediately and dispose of waste according to regulations.

Warning

Sample

Samples containing solids can produce incorrect results or block probes. For good sample quality, follow the instructions given by the primary tube manufacturers.

Warning

Light source

Danger of eye damage from the bright light of the absorbance photometer lamp. Always wear dark safety glasses when looking at the light.

Warning

Waste

Danger of infectious waste material. This can cause severe illness. Avoid direct contact with waste.

⚠ **Warning**

Carry-over

Traces of analytes may be carried over from one sample to the next. Take adequate measures to safeguard correct testing of high-sensitive methods (e.g. heterogeneous immuno-assays).

⚠ **Warning**

Cassette interchange

Do not interchange cassettes among different Cedex Bio HT systems and instruments. Each cassette rack with its cassettes may be used on one individual Cedex Bio HT instrument only. Each cassette has its own individual cassette number, which the instrument uses to identify it. Using a cassette already used on a different Cedex Bio HT instrument may lead to incorrect results.

If more than one Cedex Bio HT instrument is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual instrument (e.g. by color coding).

⚠ **Caution**

Sample

Samples containing solids can produce false results and block probes. Ensure that samples are free from insoluble particles.

⚠ **Caution**

Reagents

Danger of cauterization and skin poisoning through contact with reagents. Pay attention to the warnings on the cassettes.

⚠ **Caution**

Foam

Danger of false results. Avoid the formation of foam when handling reagents, samples, calibrators, and controls.

⚠ **Caution**

Waste material

Disposal of all waste material should be in accordance with local guidelines.

⚠ **Caution**

Correct use

Use the Cedex Bio HT system only to measure liquid samples with the provided reagents.

⚠ **Caution**

User qualification

Danger due to incorrect operation.

The Cedex Bio HT analyzer should be used by qualified users only.

Caution

Cleaning and maintenance

Incorrect cleaning and maintenance can cause damage to personnel and equipment. Perform cleaning and maintenance according to the procedures described in this publication.

Caution

Environmental conditions

Incorrect location can cause incorrect results and damage equipment components. Follow the installation instructions carefully. Relocating the Cedex Bio HT analyzer should be carried out by Roche Service only.

Caution

Cleaner

Incorrect cleaning materials can damage the Cedex Bio HT analyzer. Organic solutions damage cuvettes, tubing, and other plastic materials. Use only 70% ethanol solution to clean the equipment.

Disposal recommendations

All electrical and electronic products should be disposed of separately from the municipal waste system. Proper disposal of your old appliance prevents potential negative consequences for the environment and human health.

Disposal of Control Unit Components

Components of your Control Unit such as the computer, monitor, keyboard, etc. which are marked with the crossed-out wheeled bin symbol are covered by the European Directive on Waste Electrical and Electronic Equipment (WEEE).

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old product, please contact your city office, waste disposal service or your local Roche Support personnel.

Disposal of the Instrument

The instrument must be treated as biologically contaminated-hazardous waste.

Decontamination (i.e., a combination of processes, including cleaning, disinfection and/or sterilization) is required before reuse, recycling or disposal.

Dispose of the instrument according to local and/or labor regulations. For more information contact your local Roche Support personnel.

Disposal recommendations

All electrical and electronic products should be disposed of separately from the municipal waste system. Proper disposal of your old appliance prevents potential negative consequences for the environment and human health.

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Disposal of the Instrument

The instrument must be treated as biologically contaminated-hazardous waste.

Decontamination (i.e., a combination of processes, including cleaning, disinfection and/or sterilization) is required before reuse, recycling or disposal.

Dispose of the instrument according to local and/or labor regulations. For more information contact your local Roche Support personnel.

The electromagnetic environment should be evaluated prior to operation of the device.

This equipment has been tested and found to comply with the limits for Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interferences when the equipment is operated in a residential area. However, this equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the present user manual, may cause harmful interference to radio communications.

Uninterruptible power supply (UPS)

Depending upon the quality of electrical grounding of the local electrical power supply, an uninterruptible power supply (UPS) may be required. A UPS is not provided with the *Cedex Bio HT* analyzer. The UPS should provide at least the maximum power listed in the Technical specifications provided in this manual.

Software virus warning

Warning

Portable storage media can be infected with and transmit computer malware (for example virus, Trojan horse).
The Cedex Bio HT is not protected against malware.
The customers are responsible for IT security of their IT infrastructure and for preventing the spread of malware from system to system.

Recommendations

- Allow connection to authorized external devices only.
- Ensure that all external devices are protected by appropriate security software.
- Ensure that access to all external devices is protected by appropriate security equipment.
- Do not copy or install any software on the *Cedex Bio HT* unless it is part of the system software or you are instructed to do so by Roche Service.
- Do not move or delete any software on control units unless you are instructed to do so by Roche Service.
- If additional software is required, contact Roche Service to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless instructed to do so by the official user documentation or Roche Service.
- Exercise utmost care when using external storage devices such as USB flash drives, CDs, or DVDs. Do not use them on public or home computers while connecting to the *Cedex Bio HT*.
- Keep all external storage devices in a secure place and ensure that they can be accessed by authorized persons only.
- Use the remote services modem only for contacting Roche Service or when instructed to do so by Roche Service.

Failure to observe these recommendations may result in wrong data, lost data, or the non-availability of the system.

Warning

If this product is connected to a local area network, this network must be protected against unauthorized access. In particular, it must not be linked directly to any other network or the Internet. Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.

For further information, contact Roche Service.

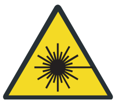
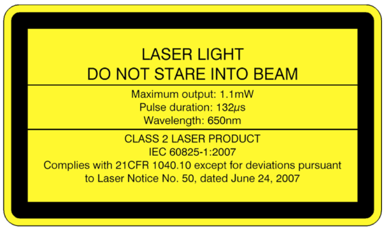
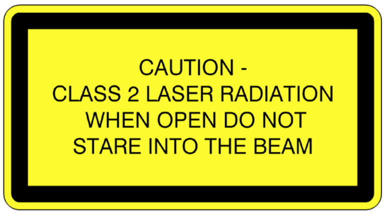
The 2nd LAN connector must only be used for Roche remote service connectivity. If a remote service connection is established over an insecure network via an AXEDA client, the device must be installed behind either a Roche "connect 2" device or a cobas link gateway. The use of an AXEDA client is the only approved and supported remote service solution. Other non-intended usage of the LAN connectors could lead to unauthorized database access resulting in possible disclosure or modification of sensitive data.

Safety labels on the system

Warning labels have been placed on the analyzer to draw your attention to areas of potential hazard. The labels for the laser transmitter are listed below according to their location on the analyzer.

The safety labels on the instrument comply with the following standards: ANSI Z535, IEC 61010-1, IEC 60417-DB-3M, or ISO 7000.

If the labels are damaged, they must be replaced by Roche Service personnel. For replacement labels contact your local Roche representative.

Safety label on analyzer	Location and meaning
  LASER LIGHT DO NOT STARE INTO BEAM Maximum output: 1.1mW Pulse duration: 132μs Wavelength: 650nm CLASS 2 LASER PRODUCT IEC 60825-1:2007 Complies with 21CFR 1040.10 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007	**Laser transmitter warning** Situated inside of the rack access panel to designate the presence of a laser transmitter. Do not stare into the laser transmitter.
 CAUTION - CLASS 2 LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM	**Laser transmitter warning** Situated outside of the rack access panel to designate the presence of a laser transmitter. Do not stare into the laser transmitter.

For details, see "Safety information for laser transmitters" on page xxi.

Safety information for laser transmitters

The *Cedex Bio HT* analyzer is a class 2 laser product. It contains one laser transmitter:

Class 2 laser transmitter inside the barcode scanner on the right side of the analyzer behind the rack access panel to scan rack, cassette, and sample barcodes.

Loss of sight due to staring into laser beam
Do not stare into the laser transmitter beam as your eyesight may be severely damaged.

Classification The mentioned class refers to the standard IEC 60825-1:

- Class 2:
  Visible lasers. Eye-safe for accidental viewing. However, it may not be safe for a person who deliberately stares into the laser beam for longer than 0.25 s, by overcoming their natural aversion response to the very bright light.

The following figure shows the position of the laser transmitter and the directions of its apertures on the *Cedex Bio HT* analyzer:

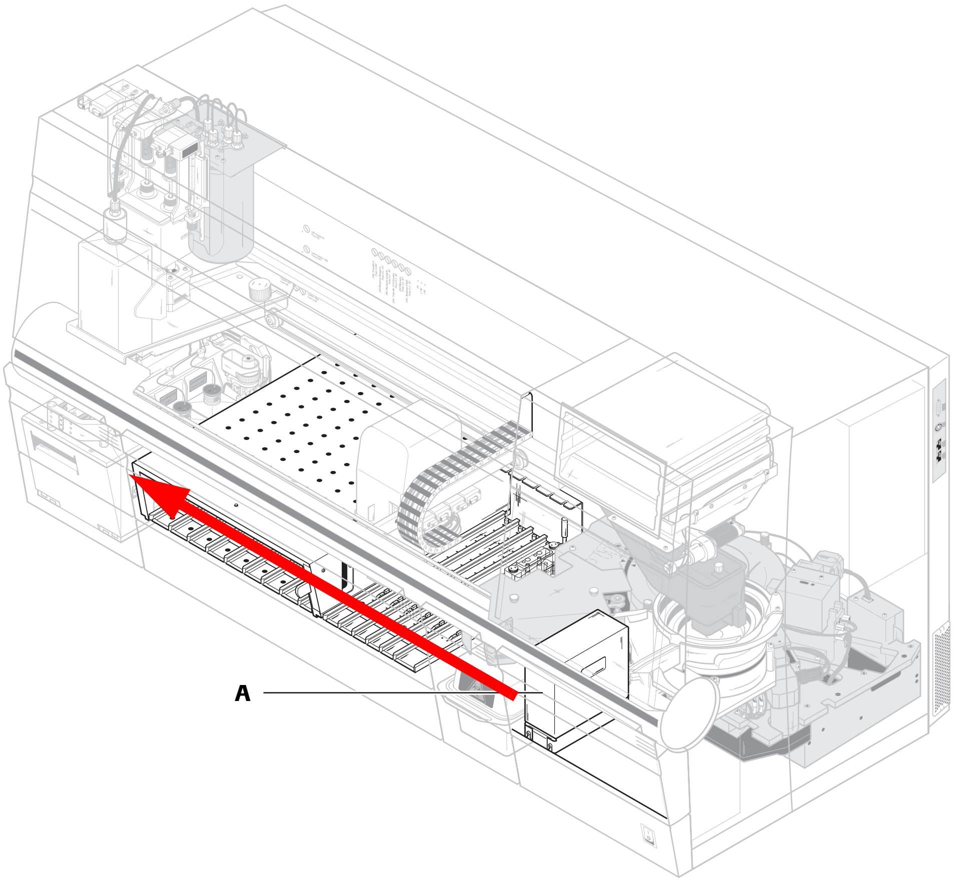


Figure 0-1 Location of laser transmitter

A *Laser transmitter behind rack access panel*

Laser	Location	Usage	Wavelength	Pulse duration	Output radiation
A	Behind rack access panel (right side)	Barcode scanner	650 nm	132 µs	1.1 mW

Overview A

Part A gives you an overview of the whole system. It includes a general introduction plus a description of the hardware and its functional systems, the user interface, and the Help system.

System overview

A quick look at the Cedex Bio HT analyzer

This chapter provides an overview of the *Cedex Bio HT* analyzer and its main features. It also provides an introduction to some of the key ideas that are developed later on in the manual.

In this chapter

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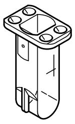
Introduction

The *Cedex Bio HT* system is a random and continuous selective analyzer designed to operate from a table top. There are three separate measurement systems supporting four different measurement principles:

Measurement system	**Measurement principle**
FP photometer	Fluorescence polarimetry
Absorbance photometer	Absorbance photometry Turbidimetry
ISE (Ion-Selective Electrode) module	Ion selective potentiometry



Samples are automatically transferred from a sample tube or cup to the module where the measurements are made. All optical measurements use the same transparent plastic containers, called cuvettes.

The graphical user interface provides quick and easy access to sample, control, and calibration data, while continuously monitoring all system functions. Color-coded icons alert you to changes in the system status. Connection to a host system allows for automatic transfer of results to and from the *Cedex Bio HT* analyzer.

What the system does

The system consists of the instrument and the data station.

The instrument runs tests on samples, calibrators, and controls, and produces the results. The data station analyses and further processes the results.

Here are just some of the actions the system performs automatically:

- Delivers the correct volumes of samples, reagents and other solutions to the measuring modules.
- Reads the barcodes on reagent cassettes, samples (if barcoded), and other solutions.
- Performs washing and cleaning cycles to minimize carry-over between tests.
- Takes the physical measurements on which the results are based.
- Calculates and ensures the integrity of the result, generating flags for suspect ones.
- Keeps track of all samples, tests, and orders on the instrument.
- Collates results into reports for printing or transmission to another computer system.
- Stores the results on each sample and test in a database.

A first look at a *Cedex Bio HT* analyzer

Instrument

The instrument carries out all test orders automatically and is equipped with measuring modules for absorbance photometry (Abs.), fluorescence polarization (FP) photometry, and for ISE measurements.

Colored LEDs (light-emitting diodes) on the rack status indicator panel on the front of the instrument tell you the current status of on-board cassette and sample racks.

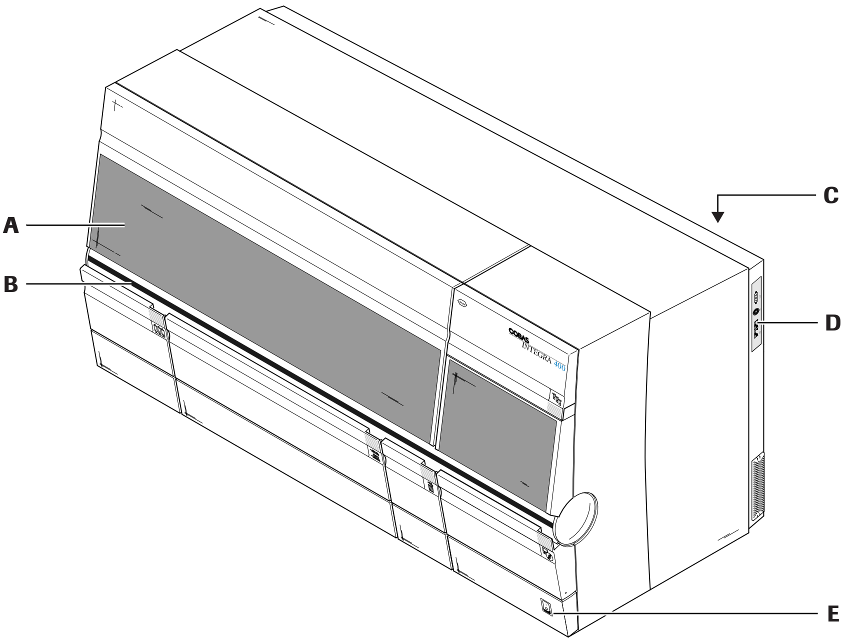


Figure 0-2 A first look at the Cedex Bio HT instrument

A *Main cover*
B *Status indicator panel*
C *External waste, water, and power connections (not shown)*
D *Data connectors (for connection to the data station and the LAN)*
E *Main switch*

The system is designed to run continuously, 24 hours a day, if necessary. However, an On/Off switch (main switch) is provided if you need to switch off the power to the system in an emergency or for troubleshooting.

"Switching on the system" on page B-31
"Shutting down the system" on page B-35

External waste, water and power connections are made at the rear of the instrument. The instrument may be connected to the laboratory waste and water system or you can use external waste and water reservoirs.

Data station

The data station comprises the elements shown below:

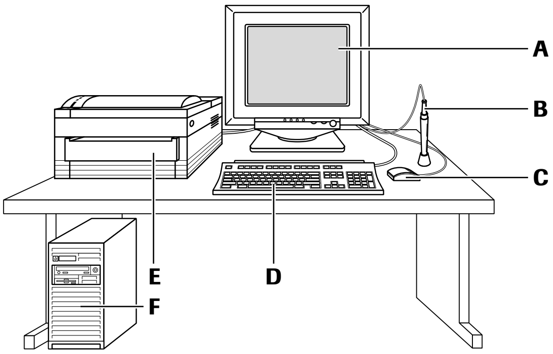


Figure 0-3 A first look at the Cedex Bio HT data station

A	*Monitor*
B	*Barcode pen (optional) or handheld barcode scanner (optional)*
C	*Mouse*
D	*Keyboard*
E	*Printer (optional)*
F	*Computer*

User interface

You can control the user interface with the mouse and keyboard. The user interface is structured as a series of work areas; the main ones are Status, Orders, Results, and Service. Each work area contains two or more tabs. By clicking a tab, you can move around the work area.

You can display any test results on the monitor or print reports containing information on samples, orders, and results. Connection to a local printer is optional.

You can manually enter orders for tests on samples in the Orders work area. Alternatively, the system receives orders electronically from a host system, if your *Cedex Bio HT* is connected to such a system.

System messages are displayed in the Messages work area, and you can communicate with other users by using the Memo Pad.

Chapter 3, "User interface"

Computer

The computer performs tasks in connection with order processing, data management, and user interface management. It makes it possible to simultaneously manage data and enter new orders. Figure 0-4 shows the appearance of the computer for *Cedex Bio HT* systems.

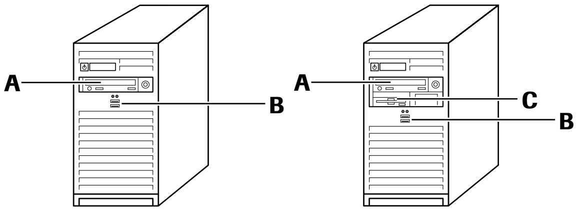


Figure 0-4 *Computer for Cedex Bio HT systems.*
Newer model (left) and older model (right).

A *DVD drive.*
Used for upgrades and data mirroring.

B *USB Ports.*
Information can be saved on USB Memory Stick.

C *Diskette drive.*
In older Cedex Bio HT systems, information can be saved on 3.5-inch diskettes.

Barcode pen or handheld barcode scanner

You use the barcode pen or handheld barcode scanner to read calibrator and control lot data located on the barcodes of the package inserts.

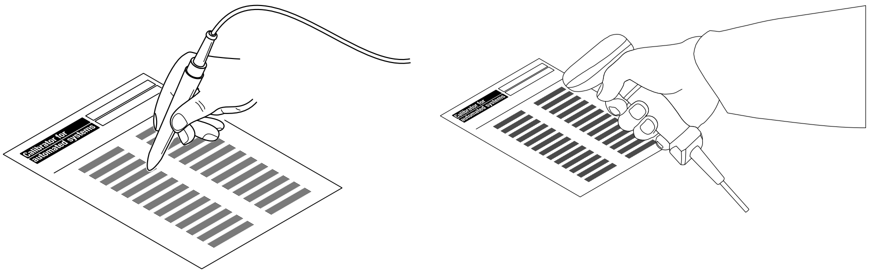

Calibrator for automated systems
Calibrator for automated systems

Figure 0-5 *Using the barcode pen (left) or handheld barcode scanner (right)*

"Setting up calibrators" on page B-154

Overview of user tasks

Figure 0-6 shows some of the main access points for tasks you perform regularly.

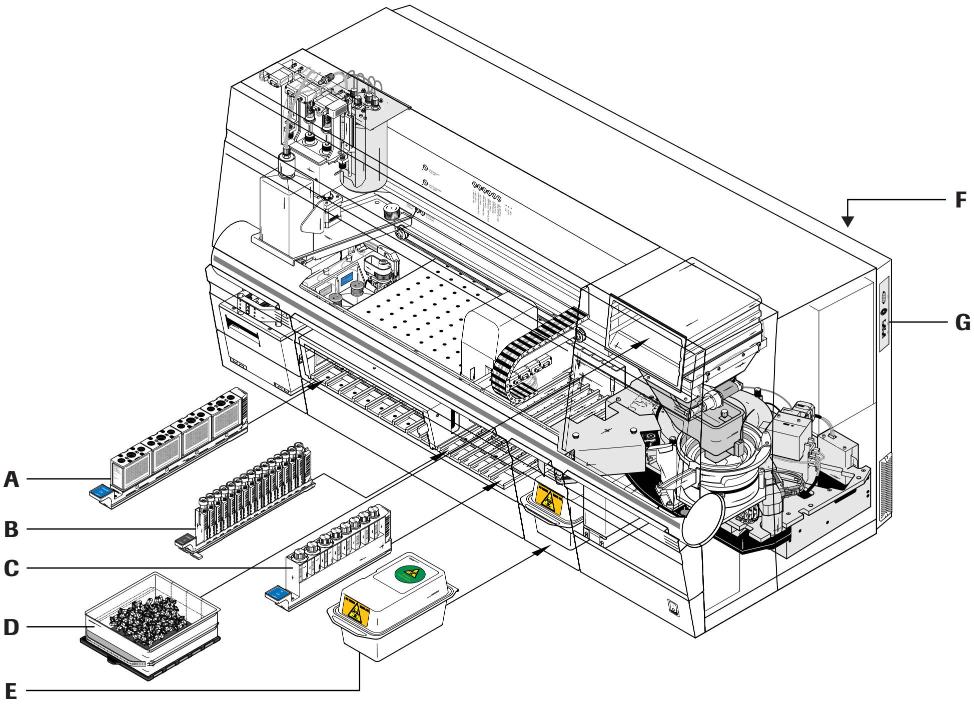


Figure 0-6 Main access points to the instrument

A *Cassette rack with reagent cassettes*

B *Sample rack with samples (or calibrators, controls, and diluents)*

C *ISE rack with ISE solutions, special cleaners, and diluents*

D *Cuvette reservoir for new cuvettes*

E *Disposable cuvette waste box (autoclavable) for used cuvettes*

F *Connections to water and waste are made on the rear panel (not shown)*

G *Data connectors*

Here are some important user tasks:

- Perform service actions.
- Prepare resources, for example, mix cassettes.
- Replace consumables such as cleaners, cuvettes and dispose of used ones.
- Print reports, for example, the Loadlist.
- Load racks containing samples, reagents (cassettes), calibrators, controls, cleaners and diluents. Remove processed racks.
- Create orders and request calibrations and controls.
- Monitor the status of the instrument: check resources and Missing & Blocked in the Status work area.
- Validate results.
- Troubleshoot problems.

- Remove waste, for example, used cuvettes or waste liquid.
- Delete results and orders.

Cleaning the instrument externally

You can clean the instrument externally with a cloth and a soap solution with mild disinfectant, or a solution of 70% ethanol.

Incorrect cleaning materials can damage the *Cedex Bio HT* analyzer.

- Do not clean the instrument while it is switched on.
- Do not use organic cleaning solvents (for example, petroleum, benzene, petrol or other solvents) because they can damage cuvettes, tubing, and other plastic materials.
- Do not use an alcohol solution with a concentration of greater than 70% alcohol, because this may damage transparent viewing windows.
- Do not use sodium hypochlorite solution because it causes corrosion on metal parts.

Service actions

You must perform all internal cleaning tasks according to the instructions given in the user documentation and provided online as part of the software assisted service actions. You review and perform service actions in the Service work area. The system prompts you when service actions are due.

Basic principles

This section provides a quick introduction to some of the key features of the instrument and how you use it.

Sample handling

Samples can be placed in 5, 5.5, 7, 7.5 or 10 mL primary tubes. Cups and Cup on Tube can be used for smaller volumes of rare samples.

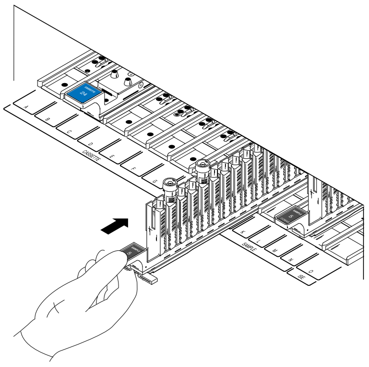


Figure 0-7 Sample rack

Sample racks allow continuous access to samples as tests are completed and new samples arrive. Samples can be barcoded to allow the positive identification of samples by the system. You can add or remove the racks as necessary. When you insert a rack, the sample barcodes are read automatically.

The samples on the left most rack (rack in slot with lowest position letter) are measured first, followed by those on the rack next to it on the right.

STATs are automatically given priority to speed up the delivery of results, while the routine workflow remains uninterrupted.

Cassettes and reagents

All tests use the same reagent cassette design. A large number of reagent cassettes specifically tailored to the *Cedex Bio HT* systems are available in an easy-to-use, easy-to-store design.

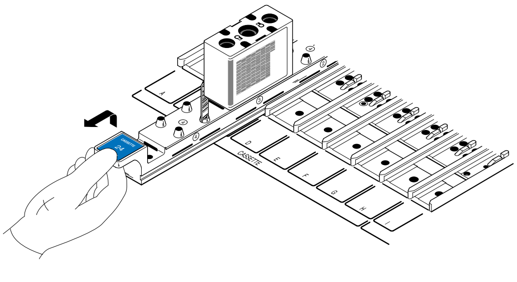


Figure 0-8 Cassette rack

You put cassettes onto a cassette rack, which you can load or remove while the system is running. Cassette labels are barcoded for fast, accurate, and secure entry of reagent data, such as the number of tests, lot number, and expiration date. .

- *When handling multiple cassette racks, wait at least three seconds before you manually handle the next rack.*
- *When inserting a cassette rack, try to tilt the rack slightly clockwise (5-10°), so that the barcode is not read at an exactly 90° angle. This can help in case of barcode reading problems due to unwanted surface reflection from a glossy barcode label material.*

Warning

Do not interchange cassettes among different Cedex Bio HT instruments. Each cassette rack with its cassettes may be used on one individual Cedex Bio HT instrument only. Each cassette has its own individual cassette number, which the instrument uses to identify it. Using a cassette already used on a different Cedex Bio HT instrument may lead to incorrect results.

If more than one Cedex Bio HT instrument is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual instrument (e.g. by color coding).

The list of on-board tests is continuously monitored; you are automatically notified when the supply is low. Color-coded cassette graphics tell you at a glance when you need to load new cassettes. Once you load a new cassette, the system automatically uses the new cassette as soon as the current one is used up. The system tracks the reagents available on board and forecasts if additional cassettes are required based on your workflow statistics. Test data is stored even after a cassette has been removed.

Calibrations and quality controls

Calibrators and quality controls use the same types of tubes and racks as samples. A refrigerated rack position improves the stability of on-board calibrators and controls.

The system performs calibrations and controls automatically according to the specification in the test definition. Alternatively, you can request a calibration or control manually. The system tells you when calibrations or controls are required and when there is not enough calibrator or control material on board to complete the request.

You can use precision, accuracy, or limit controls. You can use up to six controls per test, and you can exclude suspect controls from the statistics.

Result handling

The system automatically generates flags for all results that do not meet the required specifications. You can apply rules to ensure reliable results. On-screen Levey-Jennings plots allow a quick review of results.

Accepting results

An auto-accept feature means that you can choose whether appropriate results are accepted automatically, for example, if they have no test or quality control flags and are within range. You can display all non-accepted results (for samples, calibrators, or controls) in the user interface. For each non-accepted result, you can choose to accept the result or rerun the measurement, for example with dilution.

Caution

If you accept flagged calibration or quality control results, all results in tests that use those calibrations or controls will be suspect.

System status

The system continually monitors its own status and informs you when resources are low. You can then take the required action to keep the system running. For example, when the supply of cuvettes is low, the icon and background color of the Status button on the navigation bar change.

The Missing & Blocked tab in the Status work area, and the Worklist tab in the Orders work area tell you which tests are blocked and what you have to do to remove the block. For example, if a test cannot run because a calibrator is not on board and a calibration is overdue, the system tells you. Once you have loaded the calibrator, the system can perform the calibration and then the test.

Maintenance, service, and troubleshooting

Essential maintenance activities (referred to as service actions) are automatically tracked by the system. The system prompts you when you need to perform a service action. Online wizards guide you through the service actions, and additional step-by-step information is available in the online Help and later in this manual. The system uses workload statistics to establish the interval between service actions rather than using a fixed number of days.

For each service action performed, the system automatically logs the user, date, time, and comments in accordance with standard good laboratory practice.

Context-sensitive online Help provides troubleshooting information on hardware and software. If you cannot solve a problem yourself, you can contact Roche Service, who can (with your permission) dial into your system via the “connect 2” box or a cobas link gateway and control it remotely. You can then work together to resolve errors quickly and efficiently without waiting for an on-site service visit.

Waste disposal

The liquid waste from rinsing and cleaning operations is automatically removed from the instrument. Waste system water is transferred either to an external container or to the laboratory waste system.

Sample and reagent waste is removed with the cuvette. Used cuvettes are automatically dropped into the cuvette waste box. You have to remove the waste box and dispose of it, according to your local procedures for dealing with hazardous waste. ISE waste is transferred directly to the cuvette waste box.

Automatic start-up

At the beginning of each day, the system goes through a series of automatic service actions. Typically, these actions are performed before the work day begins, so that the instrument is ready to use when you start work.

Begin of Day

The time allocated for these service actions is called Begin of Day (BOD), and the service actions are called the BOD service actions.

While these service actions are being performed, the system cannot run any tests. However, you can terminate BOD, if you need to run urgent (STAT) orders.

System description

Finding your way around the system and its hardware

This chapter gives an overview of the hardware and provides more detailed information about the main functional systems. Some of the features described are available only if your system is configured to support them.

In this chapter *Chapter* **2**

Panels and logos ... A-16
    External connectors ... A-17
Modules and main components ... A-18
Functional systems ... A-19
    Fluid system ... A-20
    Cuvette transport system ... A-24
    Rack system ... A-27
    Robotic transfer system ... A-35
    Analyzer module ... A-37
    Computer systems ... A-40
System states ... A-41
    Transitions between states ... A-42

Panels and logos

You can open access panels when you need to work on the internal parts of the instrument. Logos on the panels help you to find your way around.

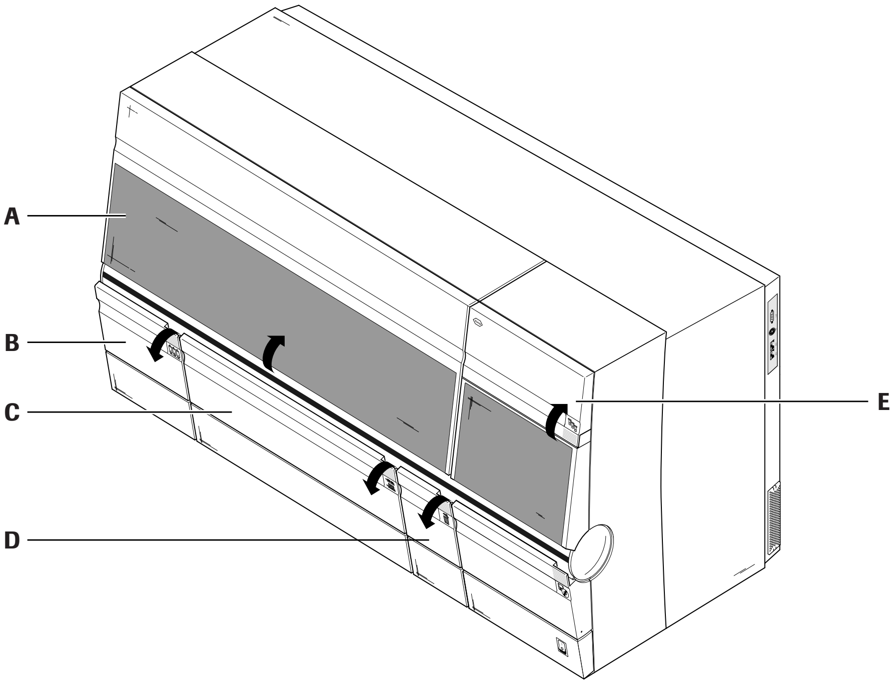
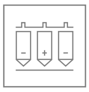


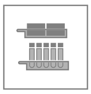
Figure 0-9 Access panels

A *Main front cover: gives access to the PCB fuses, pipette module and cleaner reservoir, transfer arm and probes, initialization posts, and wash station.*

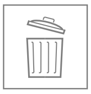
Always lift the cover as far as it will go when opening it.



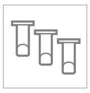
B *ISE access panel: open downwards to pull out the ISE module. See "Parts of the ISE module" on page F-5.*



C *Rack access panel: open downwards to load or remove racks. See "Loading samples" on page B-38.*



D *Cuvette waste panel: open downwards to remove and replace the cuvette waste box. See "Replacing the cuvette waste box" on page B-48.*



E *Cuvette reservoir access panel: lift up to remove the cuvette reservoir when you need to add more cuvettes. See "Refilling the cuvette reservoir" on page B-44.*

F *Service access panel: lift up to remove for example a stuck cuvette. When opening the panel make sure to secure the panel with the Locking Device Auxiliary Front Panel. When closing the panel again, first release the bracket and then close the panel slowly.*

Caution

Do not attempt to remove items from any of these locations without first referring to the appropriate section in this manual or to the appropriate topic in the online Help.

Always close any access panels you have opened when you have finished working on that part of the instrument.

The side panels are detachable. You can remove them by pulling them as shown below. When you reinstall the side panels, make sure that they click securely into place.

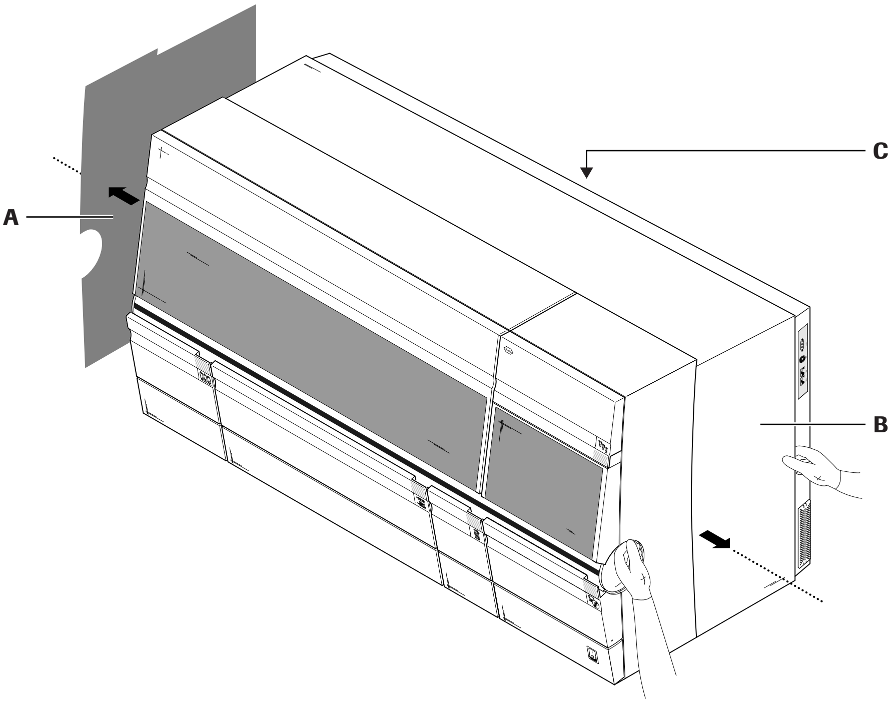


Figure 0-10 Side access panels

A *Left side panel*
Provides access to the main fuses, frequency selection switches, internal water reservoir, and drip tray.

B *Right side panel*
Provides access to analyzer rotor, absorbance photometer, FP photometer, and cuvette transport system.

C *Rear panel (not shown)*
Not detachable without a tool set. Does not provide access to any user-serviceable parts.

External connectors

The external connectors are located at the back (water, waste, and power) and on the right side (data connectors) of the instrument.

"External connectors" on page E-37

Modules and main components

Figure 0-11 shows how the modules and components are arranged inside the instrument.

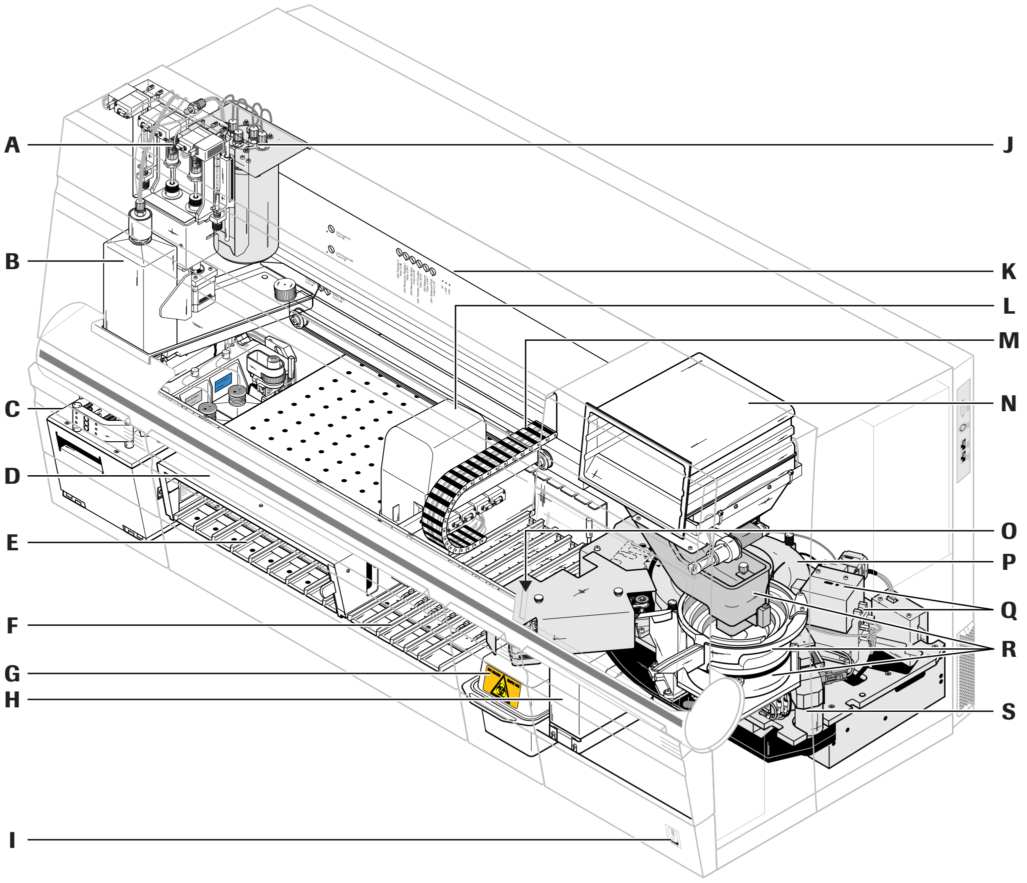


Figure 0-11 Modules and main components

A *Pipette module*
B *Cleaner reservoir*
C *ISE module*
D *Cooling box top*
E *Cassette area*
F *Sample area*
G *Cuvette waste box*
H *Barcode scanner*
I *Main switch*
J *Internal water reservoir*
K *PCB fuses*
L *Transfer head cover*
M *Transfer arm*
N *Cuvette reservoir*
O *Wash station (not shown)*
P *Rotor lid*
Q *FP photometer*
R *Cuvette transport system*
S *Absorbance photometer*

Functional systems

The *Cedex Bio HT* analyzer comprises these functional systems:

System	Function
Fluid system	Moves all the fluids used by the system, including water, samples, reagents, diluents, and cleaners.
Cuvette transport system	Provides a continuous supply of cuvettes, in the correct orientation, to the analyzer rotor; also includes the cuvette waste.
Rack system	Provides fixed slots into which different types of racks can be placed and accessed by the robotic transfer system. This also includes the racks and the barcode scanner.
Robotic transfer system	Pipettes samples, reagents, and other fluids from their containers into cuvettes for mixing so that measurements can be performed.
Analyzer module	Contains the absorbance and FP photometers, used for making measurements; also contains the workstations, which move the cuvettes for pipetting, mixing, and measuring.
ISE module	Provides the instrumentation for performing ISE (Ion Selective Electrode) measurements.
Computer systems	The circuit boards on the instrument control the instrument. The computer records measurements and calculates the results. It also controls the database that is used to keep track of all orders and results, and it manages the user interface.

Fluid system

The fluid system consists of all the valves, pumps, tubing, pipettes, fluid sensors, water and waste reservoirs, the wash station.

The fluid system transports all fluids around the system, including samples, reagents, calibrators, controls, diluents, cleaners, system water, and waste. The fluid system delivers the correct amounts of fluids for the reactions, dilutions, and cleaning.

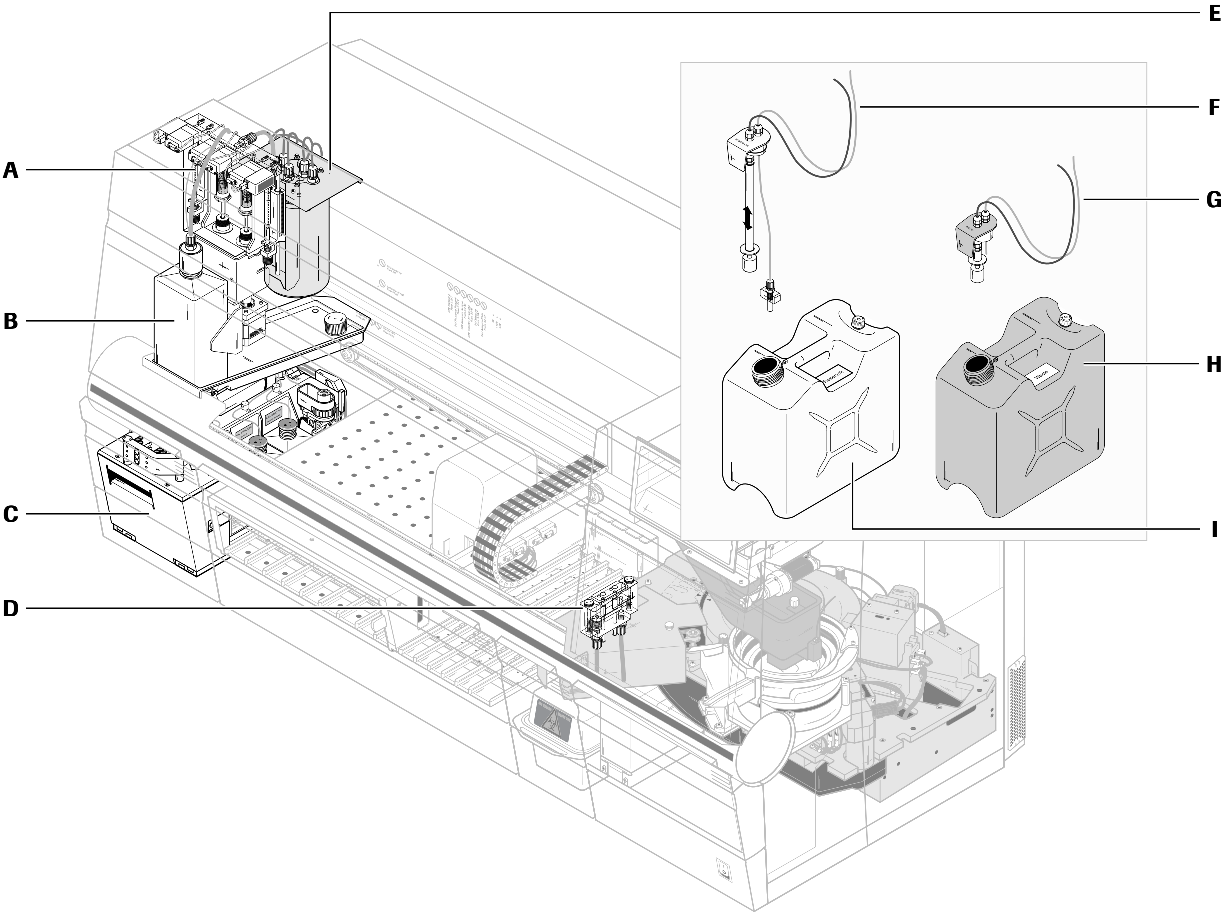


Figure 0-12 Main components of the fluid system

A *Pipette module*
B *Cleaner reservoir*
C *ISE module*
D *Wash station*
E *Internal water reservoir*
F *External water reservoir connectors (sensor and fluid)*
G *External waste connectors (sensor and fluid)*
H *External waste reservoir (yellow container)*
I *External water reservoir (white container)*

Pipette module

The pipette module contains two dosage pipettes and two wash pipettes. These are connected by tubing to the probes attached to the transfer arm. The pipettes control the pipetting action of the probes.

"Robotic transfer system" on page A-35

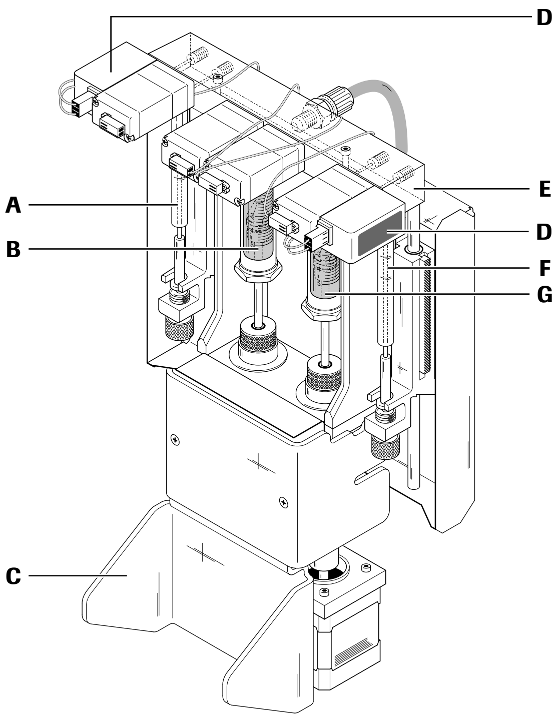


Figure 0-13 *Pipette module*

A	*Dosage pipette B*	**D**	*Clot detection sensor*	**G**	*Wash pipette C*
B	*Wash pipette B*	**E**	*Fluid control block*		
C	*Cleaner bottle housing*	**F**	*Dosage pipette C*		

The dosage pipettes control the pipetting of the required amounts of sample and reagent (or other fluid) through the probes. The wash pipettes supply water and cleaner to clean the probes in the wash station after every pipetting action and to prevent carry-over between tests.

There are several service actions you must perform related to the pipettes.

Chapter 14, "Service actions"

Wash cycle After each pipetting action, the system automatically moves the probes over to the wash station and then starts a wash cycle. During this cycle, the probes and tubing are flushed with water and cleaner. There is one wash pipe for each probe.

Wash station The wash station is made of clear plastic. All waste water from the wash station is removed to the system waste. You must disassemble the wash station for routine cleaning, according to the service action schedule.

"Clean wash station" on page D-30

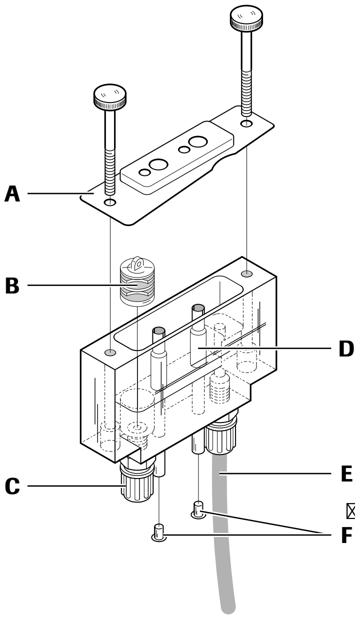


Figure 0-14 Wash station (disassembled)

A	*Plastic cover*	**D**	*Wash pipes*
B	*Noise damper*	**E**	*Overflow connector*
C	*Waste tubing connector*	**F**	*Wash pipe seals*

Water supply

The instrument can be connected to the laboratory water supply or to an external water reservoir. Water must be reagent grade, type 1.

The external water reservoir or laboratory supply feeds into an internal water reservoir located behind the pipette module.

If your system uses an external water reservoir, a sensor is connected so that the system can inform you when the water supply is nearly empty. You must clean the reservoir according to the service action schedule.

"Clean external water reservoir and fluid waste reservoir" on page D-33

Internal water reservoir

An internal water reservoir (1000 mL) feeds the wash pipettes and the ISE module with reagent grade, type 1 water. You must perform the service action Clean internal water reservoir according to the service action schedule.

"Clean internal water reservoir" on page D-27

Waste connection

The instrument can be connected directly to the laboratory waste system or to the supplied external waste container. This container has a level sensor, so the system informs you when the container is nearly full.

"Clean external water reservoir and fluid waste reservoir" on page D-33

Pumps

If the instrument is connected to an external water reservoir, the water reservoir pump brings water to the internal water reservoir. (This pump is not required for instruments connected to a pressurized supply.) A separate pump, the fluid waste pump, removes the liquid from the wash station.

The ISE module has its own pump.

Water filters

Water filters remove small particles from the water. These are located in the internal and external water reservoirs and between the water reservoir pump and the internal water reservoir. The service action tells you when you need to change these filters.

Cleaners

Probes and tubing are cleaned with water and cleaner. The cleaner reservoir contains 1000 mL of cleaner. The system informs you when you need to replace the cleaner.

"Replacing the cleaner" on page B-43

Where specified in the test definition, special cleaner is also used to improve the effectiveness of probe cleaning if particular reagent combinations are in use. The special cleaner is supplied in cassettes which are placed on the cassette rack.

Fluid waste

Waste fluids from the probes and tubing are removed automatically to the fluid waste reservoir or directly to the laboratory's sanitary waste system, if connected. Fluid waste from the ISE module goes directly to the cuvette waste box. Fluid waste from the cuvettes is automatically discarded with the cuvette.

Degasser unit

The degasser is a unit containing special filters that remove dissolved gases from the fluid system. Excessive amounts of air in the fluid system can affect the accuracy of any results obtained.

External water supply unit (optional)

This option is required when connecting the laboratory water supply to the instrument, thereby replacing the external water reservoir.

ISE module

The ISE module uses system water from the water reservoir. Fluid waste from the ISE module goes directly to the cuvette waste box.

Chapter 17, "ISE module"

Clot detection

For each sample probe, one pressure sensor for clot detection is mounted at the rear of the pipetting module. They detect clots during aspiration of samples, during washing of probes, or when initializing the system.

When a clot is detected, the probe is flushed, and a message is displayed. The run continues but no further pipetting is done from the sample cup that led to the clot detection or with the probe that is blocked. No results are printed for the sample cup associated with the clot.

When an aspirated clot clogs the probe and the automatic washing steps cannot remove it, the system stops sampling and goes into Standby as soon as all measurements are finished that currently are scheduled. To remove the clot, see

"Clot error after sample/probe washing" on page E-30

Clot detection can be enabled and disabled for each test individually in Configuration / Tests / General.

Cuvette transport system

All photometric tests (involving the FP and absorbance photometers) are performed in transparent containers called cuvettes. The cuvette transport system delivers new cuvettes to workstation In/Out, where they are fed into the analyzer rotor. Figure 0-15 shows the location of the cuvette transport system.

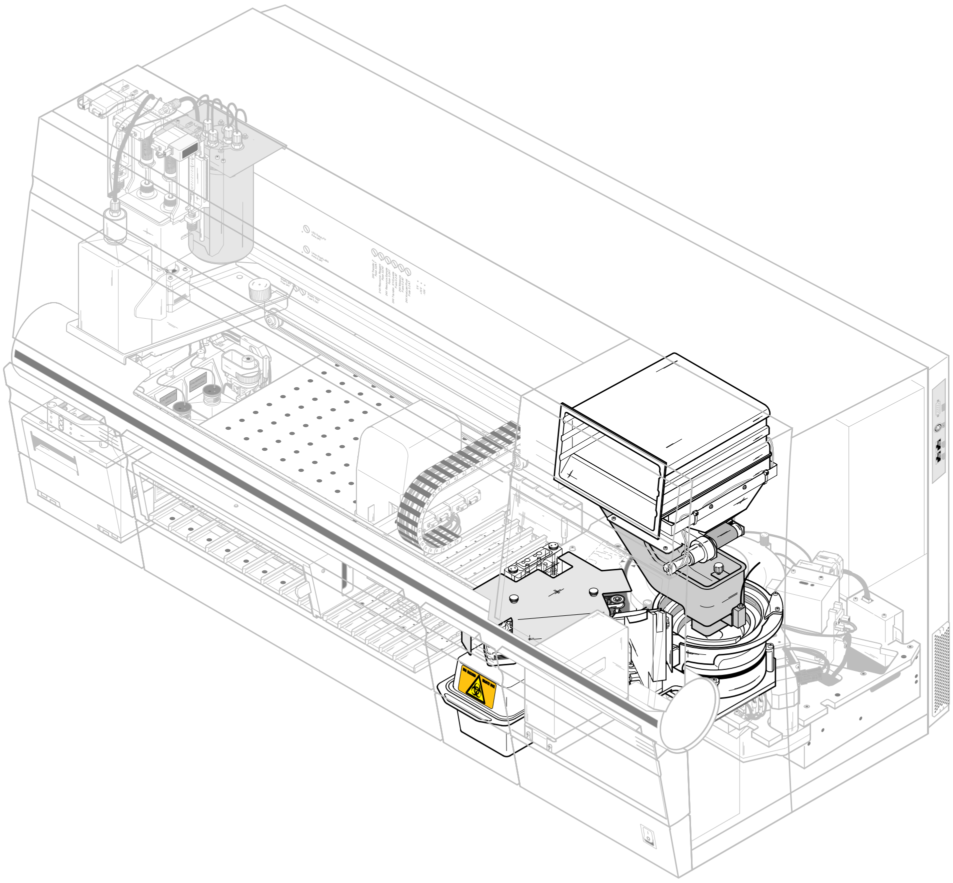
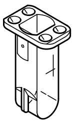


Figure 0-15 Cuvette transport system

Figure 0-16 shows the movement of cuvettes through the transport system, starting at the cuvette reservoir and ending in the cuvette waste box.



- Cuvettes are made of optical quality acrylic plastic.
- The optical path length is 5.0 mm.
- Cuvettes are disposable. They are used only once, to guarantee optical consistency and to eliminate carry-over in the cuvette.
- For optical measurements, the minimum volume of liquid in a cuvette is 120 µL, the maximum is 245 µL.
- A cuvette pack contains approximately 1000 cuvettes.

- The system quality checks the cuvettes before use by reading an empty cuvette and comparing it with an acceptable absorbance range.

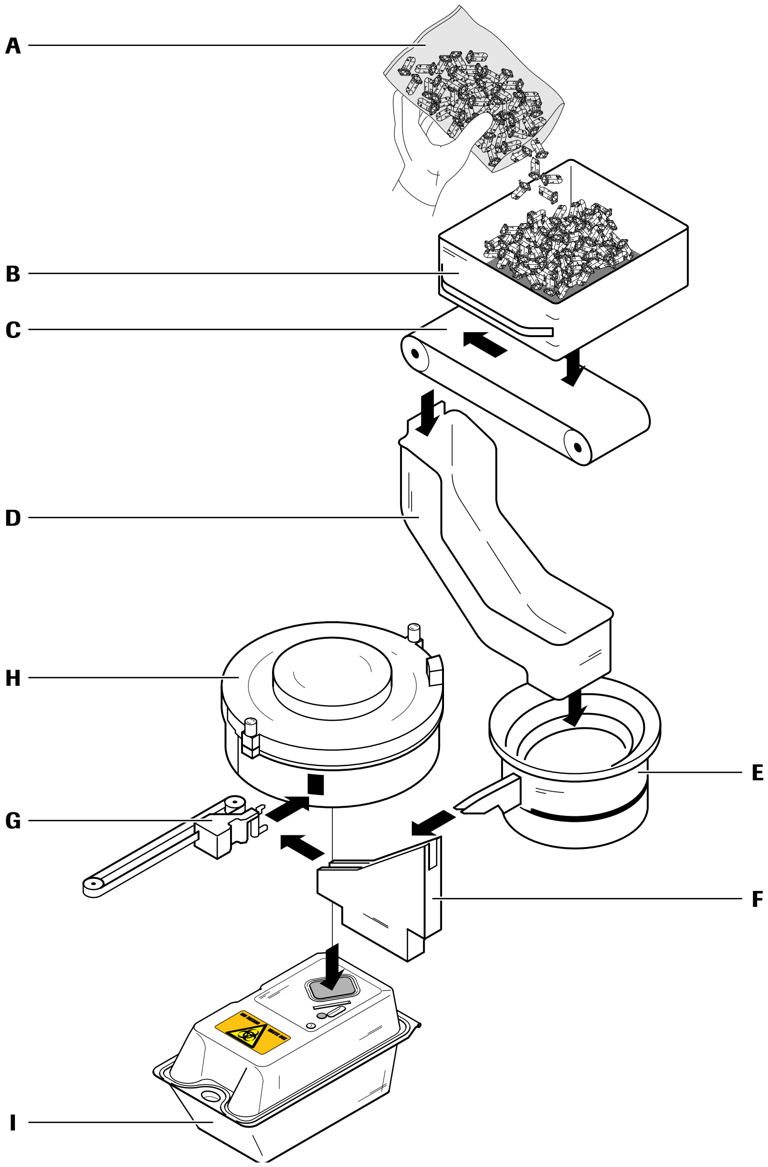


Figure 0-16 Movement of cuvettes through the cuvette transport system

A	*Pack of cuvettes*	**F**	*Cuvette buffer and slide*
B	*Cuvette reservoir*	**G**	*Workstation In/Out*
C	*Cuvette conveyor belt*	**H**	*Analyzer rotor*
D	*Cuvette feeder channel*	**I**	*Cuvette waste box*
E	*Cuvette spiral feeder*		

Cuvette reservoir

The cuvette reservoir feeds cuvettes onto the conveyor belt. You can pull out the cuvette reservoir and put the cuvettes in. You can add cuvettes while the instrument is running.

👁 *“Refilling the cuvette reservoir” on page B-44*

The cuvette reservoir holds up to 1400 cuvettes. A light barrier detects when the supply of cuvettes is low, and the system warns you when you have to refill the cuvette reservoir with new cuvettes.

Cuvette conveyor belt

Cuvettes drop from the reservoir onto the conveyor belt, which transports them horizontally so that they can fall into the feeder channel below. The movement of the belt is controlled by the number of cuvettes in the cuvette spiral feeder. This ensures a controlled supply of cuvettes; the cuvette buffer is kept full or nearly full, without the spiral feeder overflowing.

Cuvette feeder channel

The cuvette feeder channel guides cuvettes to the spiral feeder below, as they drop from the conveyor.

Cuvette spiral feeder

The spiral feeder sorts the cuvettes into the correct orientation for feeding into the cuvette buffer.

Cuvette buffer and slide

The cuvette buffer holds up to 20 cuvettes aligned in a slide, which feeds cuvettes into workstation In/Out. The cuvette buffer acts as a storage area to ensure that cuvettes are always available for the workstation In/Out.

Workstation In/Out

Workstation In/Out feeds new cuvettes into the analyzer rotor. At the start of a measurement cycle, the workstation adds a new cuvette; at the end of the cycle, it removes the used cuvettes for disposal into the cuvette waste box.

Cuvette waste box

The cuvette waste box is a disposable plastic container that can hold 1000 used cuvettes. Fluid waste from the ISE module goes directly to the cuvette waste box. The box is automatically shaken to make room for newly discarded cuvettes. You can remove the waste box, seal it, and then autoclave it.

A warning message tells you when the waste box is full and needs to be replaced.

👁 *"Replacing the cuvette waste box" on page B-48*

Rack system

The rack system allows you to physically place reagents (cassettes), samples, calibrators, controls, special diluents, and ISE solutions onto the instrument. The rack system contains slots for three different types of racks:

- Cassette rack
- Sample rack
- ISE rack

These racks are all different sizes and fit into different sized slots on the system.

A barcode scanner automatically reads barcodes on any items loaded into the rack system.

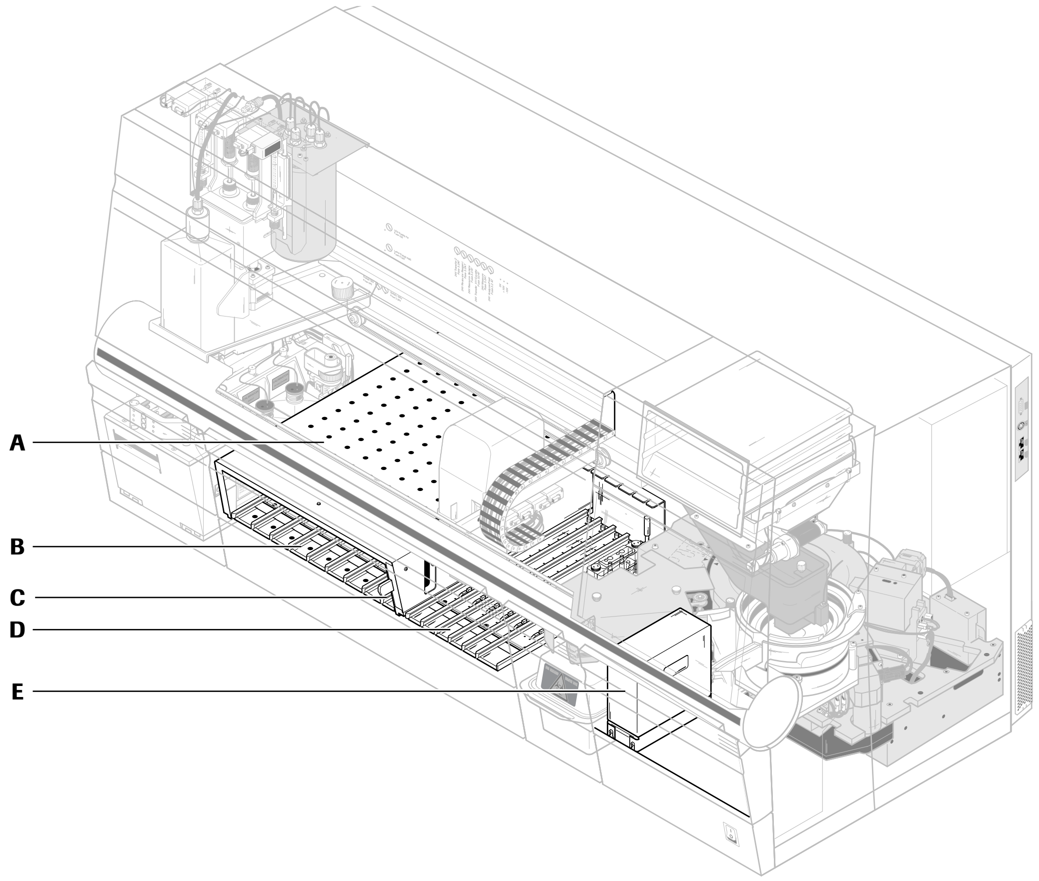


Figure 0-17 The rack system (racks not shown)

A *Cassette area cooling box*
C *Cooled sample rack*
D *Sample area*
E *Barcode scanner*
B *Cassette area*

Rack areas and platforms

You access the rack area by opening the rack access panel (see logo, left). Inside, there are two rack areas:

Cassette area	Contains the cassette rack platform. This area is enclosed by the cooling box, and the temperature inside is maintained at 10 - 15 °C. The cassette rack platform has slots for eight cassette racks and one sample rack.
Sample area	Contains the sample rack platform. This area is not enclosed by a box; the temperature is approximately room temperature. The sample platform has five slots for sample racks and an additional dedicated slot for an ISE rack.

Figure 0-18 shows the rack platforms removed from the system (left) and a schematic layout of the rack platform from above (right).

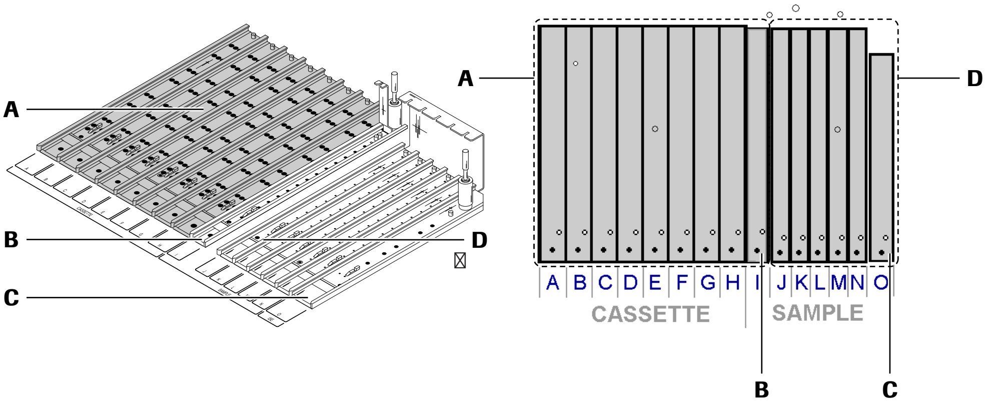


Figure 0-18 Rack platforms (callouts refer to both figures)

A *Cassette area (cooled to 10 - 15 °C).*
Slots A through H are for cassette racks.

B *Slot I in the cassette area (also cooled) is for sample racks—typically used for calibrators and controls.*

C *Slot O is for the ISE rack.*

D *Sample area.*
Slots I through N are for sample racks.

You can remove cassette platforms individually for routine cleaning as part of a service action.

"Clean instrument" on page D-36

Unlock rack tool

The unlock rack tool is supplied with the instrument. It is located on the right of the cleaner reservoir. You can use it to:

- Remove the rack platforms for cleaning.

  "Clean instrument" on page D-36

- Manually release racks.

  When the instrument is not in operation, you can release racks manually by using the unlock rack tool to press the release button shown in Figure 0-19.

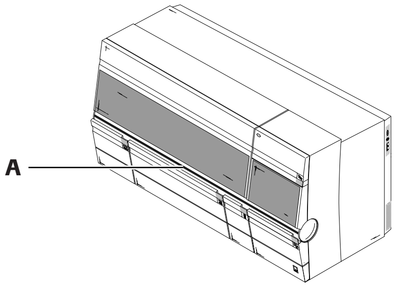
Danger

Do not *release racks manually when the instrument is in operation. If you try to press the release button while the instrument is pipetting, there is a risk of damaging your hands and the probes.*

Rack status indicators

The rack status panel (A) contains a set of small lights (LEDs—light-emitting diodes) that show the status of the rack immediately below the light.

The logo on each light tells you the type of rack (cassette, sample, or ISE). The color and whether the light is blinking or steady tells you the status of the rack.



Cassette rack Sample rack ISE rack

The following table tells you the rack states and the user actions you can perform in each state:

If you see…	This means…	User action
No light	• There is no rack in the slot.	You can insert a rack into the rack platform.
Green light steady	• The rack has been inserted correctly and is ready to be processed or… • The processing of the rack is completed.	You can remove the rack from the rack platform.
Green light blinking	• The rack is being loaded and rack identification is taking place or… • The rack is being removed.	You can still remove the rack from the platform.
Red light steady	• The rack is locked because it is being processed. Pipetting is in process or about to begin.	You cannot remove the rack while the red light is displayed.
Orange light blinking	• The rack cannot be identified because it is not defined on the system or... • The barcode scanner could not read the barcode label.	Remove the rack and define it in Configuration / Lab / Racks. Check the barcode label for damage.
	• The rack has not been properly inserted or... • The barcodes were not recognized or... • Another rack on board has the same code.	Remove and reinsert the rack. If blinking reoccurs, check the messages for the reason.

Cassettes and cassette racks

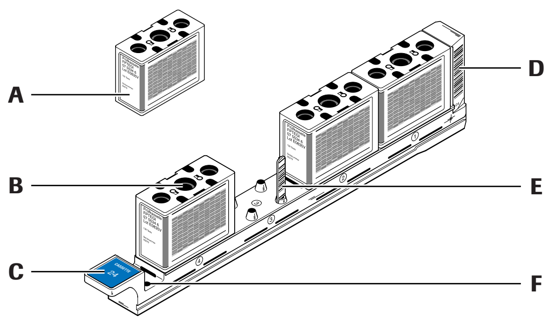


Figure 0-19 Cassette rack and cassettes

A *Cassette (removed)*
B *Vials for reagents and start reagents*
C *Rack number*
D *Rack barcode*
E *Barcode for confirming a missing cassette from this position*
F *Press button for manual release of the rack. Do not release racks manually while the instrument is in operation. See “Unlock rack tool” on page A-28.*

The reagents for a test are supplied in a single cassette. All cassettes have the same basic design.

Each cassette holds enough reagent for between 50 and 800 tests, depending on the test.

Warning

Do not interchange cassettes among different Cedex Bio HT systems and instruments. Each cassette rack with its cassettes may be used on one individual Cedex Bio HT instrument only. Each cassette has its own individual cassette number, which the instrument uses to identify it. Using a cassette already used on a different Cedex Bio HT instrument may lead to incorrect results.

If more than one Cedex Bio HT instrument is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual instrument (e.g. by color coding).

Cassette label The cassette name, lot number, expiration date, content of active ingredients, and other test specific information is written on the cassette label.

Cassette barcode The system automatically reads the following information from the barcode label:

- Article number (identifies the Roche product.)
- Cassette number
- Expiration date
- Lot number

Cassette racks A cassette rack holds up to four cassettes. Each rack is identified by a number on the front tab of the rack and a barcode label on the side. The barcode scanner reads the cassette rack IDs as the rack is inserted into the rack platform.

Integrated cassette volume check This function checks the reagent filling of each cassette. It ensures that the system correctly aspirates the number of tests the cassette is specified for.

The cassette volume check is carried out once per cassette when the cassette is placed for the first time on the instrument. Each cassette vial is checked individually by aspirating reagent at the expected filling level into a cuvette. Presence or absence of reagent is detected using the absorbance photometer.

If the integrated cassette volume check fails a message is displayed and the cassette access is denied.

The cassette volume check can be enabled in the Configuration work area (Configuration / General / System). The current status of the cassette volume check (enabled or disabled) is listed in the BOD report.

Sample racks

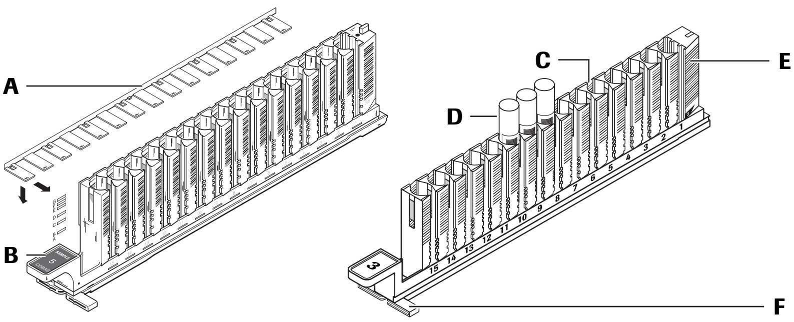


Figure 0-20 Sample racks and tube height adapter

A	*Tube height adapter (grid)*	**D**	*Tube*
B	*Sample rack label*	**E**	*Rack barcode*
C	*Barcode on an empty slot*	**F**	*Rack stabilizer foot*

A sample rack has 15 positions for tubes containing samples, calibrators, controls, or diluents. For samples, both primary and secondary tubes can be used.

Caution

You can use only one type of sample tube or cup in each rack. This is true whether the rack has been configured for a specific tube type or for a specific sample type.
You must not mix different tube types on the same rack.

Sample type specific racks are used when the barcodes on the samples do not contain sample information. This enables the system to identify the sample type.

Tube height adapter (grid) You can adjust the height of the tubes in the rack by using a grid device. You can check or change the grid position (if you have the correct user access level on your system) in Configuration / Lab / Racks.

Rack number and rack code Each rack has a number on the front tab of the rack and a barcode on the side. The barcode scanner reads the sample and sample rack barcodes as you insert the rack into the sample rack platform.

In the rack definition dialog box (Configuration / Lab / Racks), each rack is assigned the following parameters:

Parameter	Description
Rack number	A three-digit number corresponding to the number you see on the sample rack label.
Rack code	The number automatically read from the barcode label on the rack as it is inserted into the rack platform.
Rack name	A user-defined value that typically tells you the purpose of the rack. For example, a rack reserved for calibrators and control might be assigned a rack name of CAL-QC.
Tube type	Select the tube type for the specified rack.
Sample type	Select the sample type for the specified sample rack.
Barcode	If the box is selected, the barcode labels on the samples, tubes, and adapters are read.

ISE rack

You can assign these positions in Configuration / Lab / Reserve Positions.

Slot O on the sample rack platform is reserved for the ISE rack.

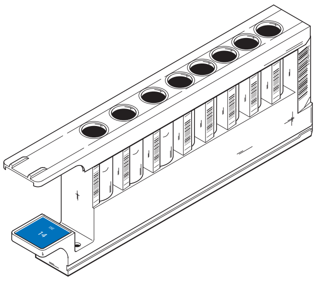


Figure 0-21 ISE rack

Chapter 17, "ISE module"

Tubes and cups

You can use several different types of tubes and cups on the system, although you must ensure that you use only types that have been predefined for your system. This is done for you at installation by Roche service personnel.

The following table summarizes which type of containers you can (or must) use with each type of solution on the system:

Solution	Container(s)
Samples	Primary or secondary tubes or cups
Controls	Tubes or cups
Calibrators	Tubes or cups
Diluents	Bottles on the ISE rack or tubes on a sample rack **Note**: It is possible but not recommended to place 9% NaCl solution or hemolysing diluent on a sample rack. Always place hemolysing diluent in its original bottle and 9% NaCl solution in its original bottle or in a 25 mL dead volume optimized bottle on the ISE rack.
Cleaners	Cleaner reservoir for the default cleaner Cleaner cassettes on the cassette racks
ISE solutions	On the ISE module itself or in bottles on the ISE rack

Sample tubes and cups

The system can use both primary and secondary tubes. The following types of tubes are predefined:

- COBAS cup
- Eppendorf cup
- Sarstedt 5 mL
- Sarstedt 5.5 mL
- Sarstedt 7.5 mL
- Vacutainer 7 mL
- Vacutainer 10 mL

You can use other types of tubes, but these must be defined for your system in Configuration / Lab / Sample Tubes.

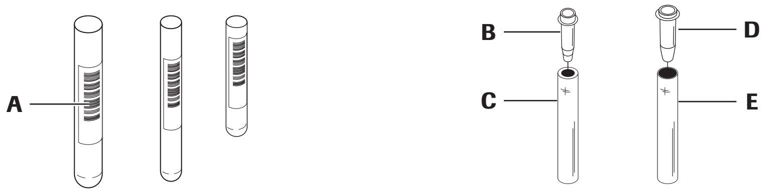


Figure 0-22 Sample tubes and cups

A	*Sample barcodes on tubes*	**D**	*Any microcup (for example, Eppendorf cup)*
B	*COBAS cup*	**E**	*Wide end of the cup adapter*
C	*Narrow end of the cup adapter*		

Cup adapters

For smaller quantities of samples, you can use COBAS cups, Eppendorf cups, or other commercially available microcups.

You insert these cups into an adapter, using the narrow end for COBAS cups and the wide end for Eppendorf cups. You can attach a barcode on the side of the adapter. You then insert the adapter together with the cup into a free slot on the rack

.

Caution

Do not put COBAS cups into the wide end of the cup adapter. This can cause pipetting errors leading to unreliable results.
Remove all caps from the sample tubes and cups (primary or secondary) before placing the rack with the tubes or cups inside the instrument. Otherwise, you may damage or block the probe or obtain unreliable results due to level detection problems.

You can define *one* microcup as the Cup on Tube, that is the cup you will use on top of a tube (Configuration / System / Lab / Sample Tubes / Cup on Tube).

Diluent handling

Accelerator I is supplied in vials that are incompatible with the ISE rack. Therefore, to use Accelerator I on the ISE rack, pour it into extra bottles prior to placement.

If you prepare the 9% NaCl diluent yourself, you must use dead volume optimized bottles.

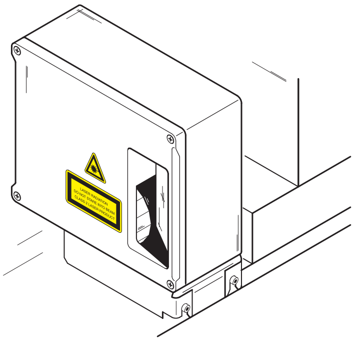
The following table lists possible placements of available diluents on the *Cedex Bio HT* analyzer:

Diluent	Placement	Capped
NaCl Diluent 9%	ISE rack	Yes
	Sample rack	No
Pyridoxal phosphate liquid	ISE rack	Yes
	Sample rack	No
Accelerator I	ISE rack	No
	Sample rack	No
HbA1c Hemolysis Reagent	ISE rack	Yes
	Sample rack	No
ISE Deproteinizer	ISE rack	Yes
ISE Etcher	ISE rack	Yes
ISE Activator	ISE rack	No
ISE Solution 1	ISE rack	Yes
ISE Solution 2	ISE rack	Yes
ISE Solution 3	ISE rack	Yes

The onboard stability of the diluents is monitored by the system software when the diluent is placed on the ISE rack. In contrast, on sample racks the onboard stability cannot be monitored by the system. In this case, it has to be monitored by the operator.

For details about the onboard stability, refer to the individual Method Sheets.

Barcode scanner



Barcodes contain machine-readable information in the form of black and white stripes. All cassettes are barcoded so that they are automatically recognized when you load them on board. You can attach barcodes to sample tubes and cup adapters to identify samples, calibrators, controls, and diluents.

The barcodes supported are:

- Code 2 of 5 Interleaved
- Codabar (code 2 of 7)
- Code 128
- Code 39 (3 of 9 interleaved)
- UPC (A, E)
- EAN

You can select other barcodes from the ones that are predefined in Configuration / General / Barcode, if you have the required user access level.

Barcode reading can individually be set for each rack group (Configuration / Lab / Racks).

Samples are automatically recognized when they are loaded, if the sample tubes have barcodes on them and either of the following is true:

- The barcode contains sample type information.
- The barcode does not contain sample type information, but the sample is assigned to a rack that is sample type specific.

For samples without barcode labels, you can use the Automatically Assign Rack Positions feature, and then accept the proposed assigned rack positions in the Sample Handling dialog box.

"Loading samples" on page B-38

Tips

- Insert only one rack at a time. The barcode scanner reads across the whole rack area, and therefore a second rack could be obscured by the first. Wait at least three seconds before the next rack movement.
- When you insert a rack, the rack is blocked momentarily to allow the scanner to focus on the correct rack slot and rack barcode.
- Insert the rack in one clean motion; stopping halfway generates an orange blinking light on the status indicator.
- When removing a rack, remove it completely. If you leave the rack partially removed, other racks being inserted may be not be seen properly by the scanner.

Robotic transfer system

The robotic transfer system automatically controls and moves the probes to the correct positions for all pipetting and cleaning actions. There is one transfer arm to which the two probes are attached. The transfer arm moves in a horizontal (X- and Y-axes) plane; the probes also move up and down (Z-axis). Figure 0-23 shows the parts and location of the transfer system, including the initialization posts.

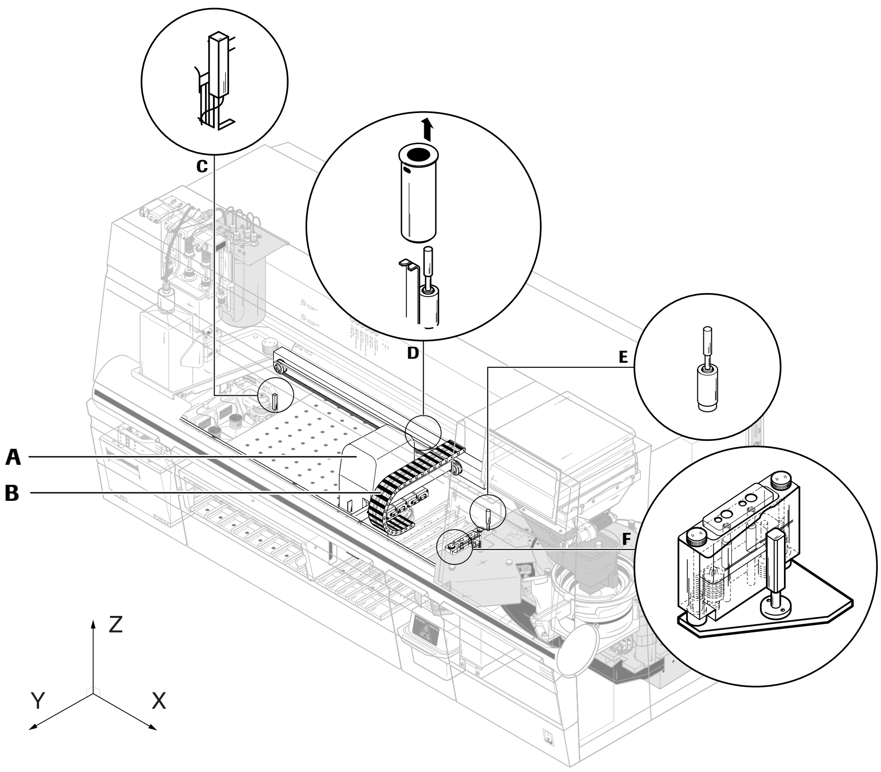


Figure 0-23 Transfer system and initialization posts

A	*Transfer head cover*	**D**	*Cassette area initialization post and protective sleeve (not visible in the main system part of the picture)*
B	*Transfer arm*	**E**	*Sample area initialization post*
C	*ISE initialization post*	**F**	*Wash station initialization post (not visible in the main system part of the picture)*

Coordinates

System messages relating to the transfer arms often refer to a specific direction of movement. If you stand facing the instrument, the direction axes are defined as follows:

X-axis	Left-to-right motion
Y-axis	Backwards-and-forwards motion
Z-axis	Up-and-down motion

Probes

There are two probes named probe B and probe C. Their names are based on the workstation (B or C) where they pipette the required amounts of fluids into a cuvette.

The probes are thin hollow metal tubes attached to the transfer arm and directly connected by tubing to the pipettes in the fluid system. The dosage pipettes control the volumes of liquids pipetted.

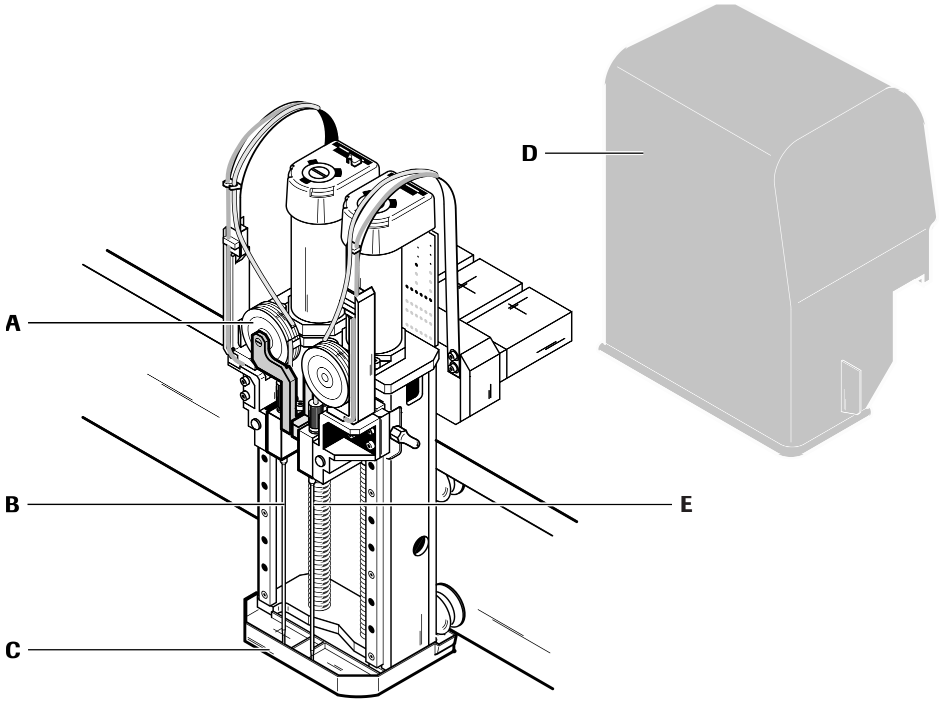


Figure 0-24 Transfer head with the cover removed

A	*Sample loop holder*	**D**	*Transfer head cover (removed)*
B	*Probe C*	**E**	*Probe B*
C	*Splash guard*		

Probe B

- Pipettes reagents (and sample for some tasks).
- The pipetting takes place at workstation B.
- Is located nearest to you when you open the main front cover.

Probe C

- Pipettes both reagents and samples.
- The pipetting takes place at workstation C.
- Is located furthest away from you when you open the main front cover.

Sample loops The sample loops are coils of tubing long enough to hold any liquid pipetted and to allow a complete change-over of fluid.

Splash guard The splash guard is a black plastic tray that prevents direct user access to the probes, thus protecting them from accidental damage. It also catches any drips of liquid on the outside of the probes, preventing contamination of other parts of the instrument.

The system informs you when the splash guard needs cleaning as part of the service schedule.

“Clean probes and splash guard” on page D-24

Initialization posts

The initialization posts are fixed surfaces that the instrument uses as transfer reference points during initialization. There are four initialization posts:

- ISE module
- Cassette area
- Sample area
- Wash station

Figure 0-23 on page A-36

The positioning of the probes depends on the initialization posts; the posts must therefore be kept clean. In particular, you clean the posts as part of the service action Clean instrument and at other times if you see that they are not clean.

"Clean instrument" on page D-36

Analyzer module

The analyzer module is the part of the instrument where the reaction between the sample and the reagent(s) takes place and where the photometric measurements are made. Figure 0-25 shows the main external components of the analyzer module.

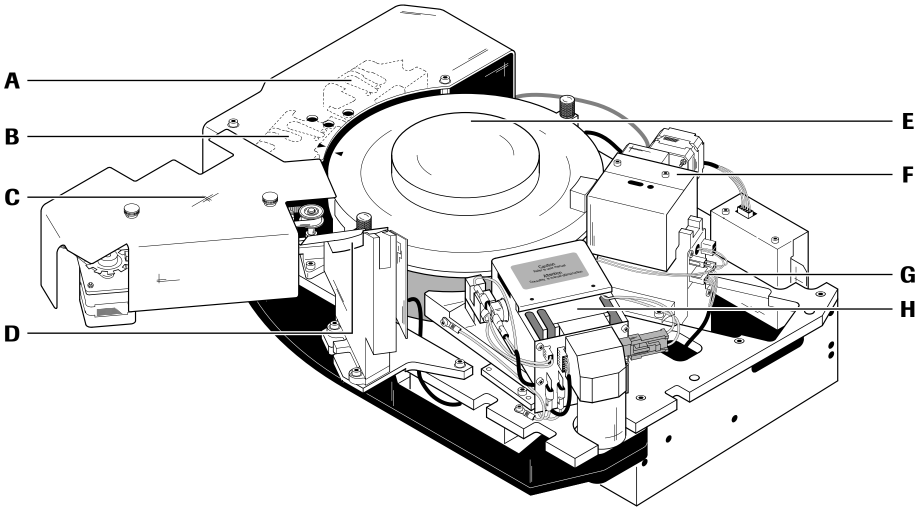


Figure 0-25 Analyzer module with workstations and photometers

A *Workstation C*	**E** *Rotor cover*
B *Workstation B*	**F** *Workstation FP*
C *Workstation In/Out*	**G** *FP photometer*
D *Cuvette buffer and slide (cuvette transport system)*	**H** *Absorbance photometer*

Analyzer rotor

The analyzer rotor is a ring-like assembly that has slots into which cuvettes are loaded automatically from workstation In/Out. The rotor holds up to 71 cuvettes. As the rotor turns, it moves the cuvettes to the appropriate locations so that pipetting operations can be performed and photometric measurements can be made.

Typically, these operations occur in parallel, that is, pipetting can be carried out on one cuvette, while another is undergoing photometric measurements.

Temperature The temperature inside the analyzer is maintained at:

- yellow icon 37 °C ±0.2°C
- red icon 37 °C ±0.5 °C.

If the temperature goes outside these limits, the system automatically informs you.

👁 *“Analyzer tab” on page B-76*

Cycle time

The cycle time of the analyzer rotor is 10.6 seconds. The whole operation of the system is based on this cycle time, with each measurement taking a whole number of cycles. A cycle begins with workstation In/Out loading a new cuvette onto the rotor. Afterwards the rotor turns in an anti-clockwise direction. At cycle 70, the cuvette is removed by workstation In/Out and dropped into the cuvette waste.

Workstations

The workstations handle the cuvettes, loading them onto the analyzer rotor and removing them temporarily for pipetting, mixing, and FP measuring.

Workstation In/Out

Workstation In/Out moves new cuvettes, one at a time, from the cuvette buffer slide and loads them onto the analyzer rotor. When all the measurements for a particular cuvette have been completed, workstation In/Out removes the used cuvette and drops it into the cuvette waste box.

Workstation B

Workstation B temporarily removes a single cuvette from the rotor so that the cuvette can be accessed by probe B, for reagent or sample pipetting.

When the pipetting is finished, the cuvette is rotated elliptically in the workstation to mix the fluids. The cuvette is then put back onto the rotor to be moved around to one of the photometers for the measurement phase.

Workstation C

Workstation C temporarily removes a single cuvette from the rotor so that the cuvette can be accessed by probe C, for reagent, sample, or diluent pipetting.

When the pipetting is finished, the cuvette is rotated elliptically in the workstation to mix the fluids. The cuvette is then put back onto the rotor to be moved around to one of the photometers for the measurement phase.

Workstation FP

This workstation removes a single cuvette at a time from the rotor so that fluorescence polarization measurements can be made in the FP photometer. When the measurements are complete, the workstation returns the cuvette to the rotor.

At the absorbance photometer, the measurement is made with the cuvette still in the rotor.

Photometers

There are two photometers: one for absorbance measurements and one for fluorescence polarization measurements.

Absorbance photometer

For each cuvette slot, the absorbance photometer measures light intensity at 12 different wavelengths. The light beam from the absorbance halogen lamp passes through the cuvette and then into a photodiode array where the measurements are made.

The absorbance photometer makes both absorbance and turbidimetric measurements.

For absorbance measurements:

- Absorbance readings are linear in the range 0.0 through 2.0 absorbance with less than 1% deviation at a path length of 0.5 cm.
- The measurement system uses blank positions on the rotor to monitor the background signal for the electronic adjustment of drift.
- The measurements are taken without removing the cuvette from the analyzer rotor.

The life expectancy of the absorbance halogen lamp is 800 hours. The system informs you when you need to replace the lamp.

“Replace Abs. halogen lamp” on page D-51

Wavelengths for the absorbance photometer

The absorbance photometer makes measurements at the following wavelengths:

- 340 nm
- 378 nm
- 409 nm
- 480 nm
- 512 nm
- 520 nm
- 552 nm
- 583 nm
- 629 nm
- 652 nm
- 659 nm
- 800 nm

All wavelengths are measured at the same time, but only one wavelength (for monochromatic measurements) or two wavelengths (for bichromatic measurements) are used.

FP photometer

The FP photometer makes measurements on samples based on the principle of fluorescence polarization. The cuvettes are temporarily removed from the rotor by workstation FP and then the FP measurements are made.

For FP measurements:

- The light source for the FP photometer is a blue LED.
- The photometer uses a polarization filter which rotates to let through either the parallel or the perpendicular component of the light.
- The measurements are made with a photomultiplier tube, and take two seconds for each component.
- Assays are based on the competitive binding principle.
- The average throughput is up to 170 tests per hour.

Computer systems

The system contains two computer systems: one - the circuit boards in the instrument - for controlling the automatic operations of the instrument, the other - the computer of the data station - for processing data and managing the user interface.

The data station computer runs under Windows XP. This system includes:

- Color monitor
- Standard US keyboard
- Mouse
- 3.5 inch disk drive (no longer included for data station model rp5800 DS and later)
- DVD drive (R/W)
- Two hard disks
- 2 serial interfaces
- Parallel printer port
- Analog modem connector
- LAN connector
- USB Ports
- 2nd LAN connector

The 2nd LAN connector must only be used for Roche remote service connectivity. If a remote service connection is established over an unsecure network via an AXEDA client, the device must be installed behind either a Roche “connect 2” device or a cobas link gateway. The use of an AXEDA client is the only approved and supported remote service solution.

Warning

Other non-intended usage of the LAN connectors could lead to unauthorized database access resulting in possible disclosure or modification of sensitive data.

Processing data

Working data is stored in a database on the hard disk of the data station computer. This includes sample and order information and results. Raw data, that is, the measurements taken by the instruments, is stored only short term and is then deleted. The results calculated from the measurements are stored longer term.

Backups The data station computer maintains a backup of all current data. You can start this manually from the service action Backup data or you can configure this as a Begin of Day action. A backup can take more than 10 minutes to complete, during which time the instrument cannot run any tests.

In addition, the computer has a 3.5 inch disk drive (before model rp5800 DS), a USB Port and a DVD drive that can be used for:

- Loading updates to software and help.
- TAS (test application software) updates.

The disk drive or a USB Memory Stick can also be used for archiving data for long term storage and retrieval.

Electronics

Control of the many automatic systems within the instrument is performed by a set of electronic printed circuit boards (PCBs). These are located in a controller rack in a closed cabinet above the cassette and sample areas. The PCBs are protected by fuses, each of which must have the correct rating. The fuses are user replaceable.

“Checking and replacing fuses” on page E-40

System states

The current state of the system determines what actions you can perform. You can force some changes of state by pressing the function keys F11 and F12 or by clicking the Start and Stop buttons on the navigation bar; all other changes are automatic. Figure 0-26 shows some of the states and how the system moves between them. The boxes represent the states, and the arrows represent transitions between states. The icons represent the Status button on the navigation bar when the system is in that particular state.

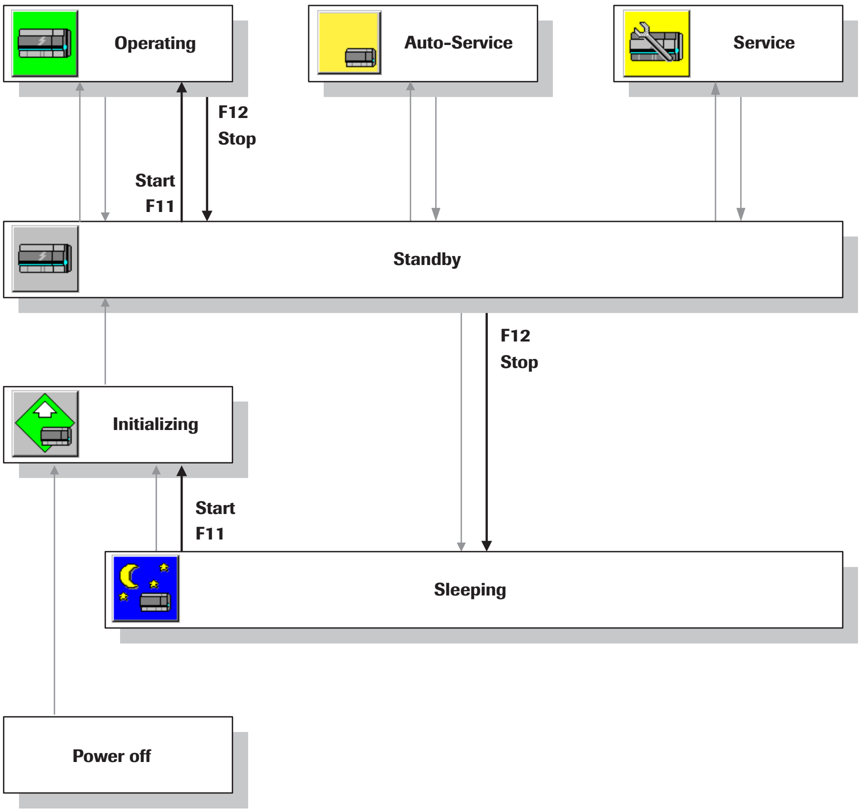

Operating
Auto-Service
Service
F12
Stop
Start
F11
Standby
F12
Stop
Initializing
Start
F11
Sleeping
Power off

Figure 0-26 System states (not all states are shown)

→	Automatic transition
➞	Manual transition (user action)
F11	START key (on the keyboard)
F12	STOP key (on the keyboard)
Start	Start button (on the navigation bar)
Stop	Stop button (on the navigation bar)

“Starting up and logging on to the system” on page B-31

Transitions between states

The following table shows the icons on the Status button (and the predominant background color) for the main transitions between system states (state 1 to state 2).

State 1		**State 2**	**Comments**
Power off	➔	Initializing (green)	Turn the power on by using the main switch on the front of the instrument.
Initializing (green)	➔	Standby (gray)	This transition is automatic, that is, when the system has finished initializing it goes into Standby. This takes a few minutes to complete.
Standby (gray)	➔	Operating (green)	This transition is automatic, if Autostart is enabled (Configuration / General / System). Alternatively, press F11 or click Start to start processing tests.
Operating (green)	➔	Standby (gray)	You can force the system into Standby by pressing F12 or clicking Stop. Alternatively, the system automatically goes into Standby either after a user specified period of inactivity or at a specific time.
Standby (gray)	➔	Sleeping (blue)	You can force a system to go from Standby into Sleeping by pressing F12 or clicking Stop. Alternatively, the system automatically goes into Sleeping after user-specified period.
Sleeping (blue)	➔	Initializing (green)	The system automatically initializes when a rack is inserted or when it is time for the Begin of Day actions. Alternatively, you can force the system from Sleeping into Initializing by pressing F11 or clicking Start.
Standby (gray)	➔	Service (green)	The Service icon is displayed when the system (or a user) is performing a service action. The system must be in Standby before you can start manual service actions.
Service (green)	➔	Standby (gray)	The system automatically goes to Standby when the service action is complete.
Standby (gray)	➔	Auto-service (green)	Auto-service means the system is automatically performing Begin of Day actions. If the system is in Operating, the Begin of Day service actions are not performed until the system goes into Standby. System automatically goes into Standby after completing BOD actions.

Tip

The following parameters concerning system states are defined in Configuration / General / System:

- End of Sequence
- Autostart
- Sleeping Mode
- BOD

You can review these parameters, to alter them you must have the required user access level.

User interface

An overview of the Cedex Bio HT software

You control the day-to-day operation of the instrument through the *Cedex Bio HT* user interface. This chapter describes the main features of the user interface and how to move between the main work areas. It also provides some tips to help you work more efficiently.

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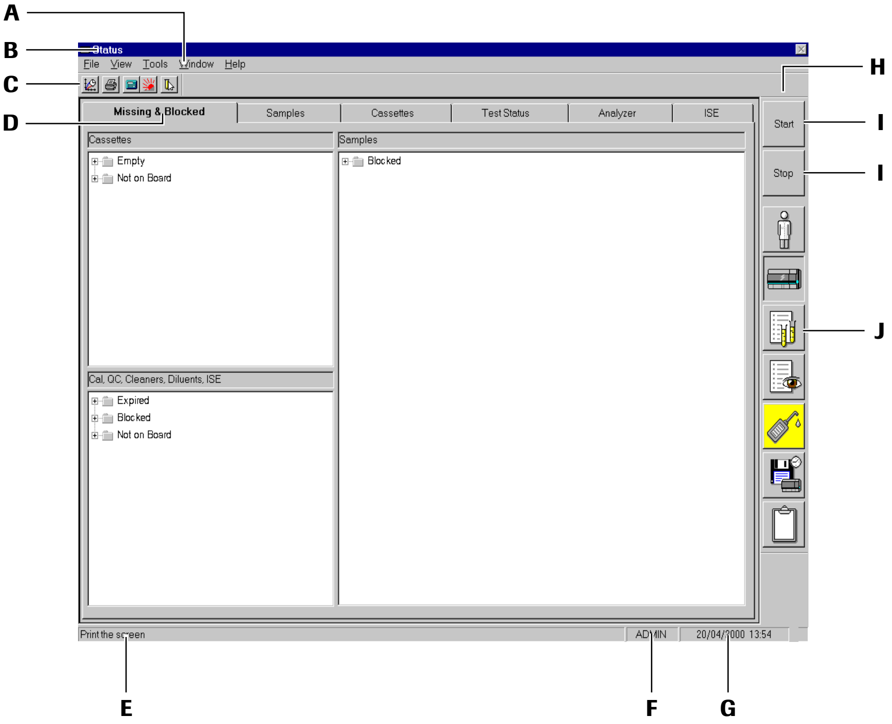
A first look at the user interface

When you have logged on, the Status work area is displayed.

“Logging onto the system” on page B-33

The following picture shows the main features of a work area:


A
B
C
D
Status
File View Tools Window Help
Missing & Blocked
Samples
Cassettes
Test Status
Analyzer
ISE
Cassettes
Empty
Not on Board
Samples
Blocked
Cal, QC, Cleaners, Diluents, ISE
Expired
Blocked
Not on Board
H
Start
I
Stop
I
J
Print the screen
ADMIN
20/04/2000 13:54
E
F
G

A *Menu bar*
Click any item to display the corresponding menu.

B *Work area name*
Name of the current work area.

C *Toolbar*
Click a button to run the corresponding command.

D *Tab name*
Change the tab displayed by clicking another tab, for example, Cassettes.

E *Status bar*
Short text for messages and expanded tooltips are displayed here.

F *User ID*
For the currently logged-on user.

G *Date and time*
Date and time (automatically updated) displayed in the current Windows format.

H *Navigation bar*
Click a navigation button to open the corresponding work area.

I *Start and Stop buttons*
Start or restart a run; interrupt or stop sampling once the current actions are finished

J *Navigation button*
For example, click this button to open the Orders work area.

Work areas

A work area is a window where you can perform a set of generally related tasks. You can open a work area by:

- Clicking one of the buttons on the navigation bar.
- Pressing the appropriate function key (see below).
- Using the Window menu from the menu bar.

Navigation button	Work area	What you can do…
	Messages Shift + F5	Display system messages. You can also review the message log for all the system messages, particularly those that have resulted from errors or problems.
	Status F5	Display the status of the system, including the status of samples, calibrators, quality controls, diluents, and cassettes. You can check the status of any test and find any missing or blocked items for the current worklist.
	Orders F6	Check the status of the orders, create new orders and make requests for calibrations and quality controls. You can create and modify a set of details about an order (order demographics).
	Results F7	Review any results that have not been automatically accepted by the system. You can also review accepted results (result history) for samples, calibrations, and quality controls.
	Service F8	Review when scheduled service procedures, called service actions, are due and perform them, if necessary.
	Configuration Shift + F8	Set up system parameters that define how the system runs. For example, you can specify the quality controls you are going to use with a particular test. You cannot use these functions, unless you have the required user access level, which your system supervisor defines for you.
	Memo pad Shift + F7	Leave messages on the system for other users. You can type in the text manually and indicate if the memo is urgent.

Menu bar

You can use the menu bar, which is available in the Status, Orders, Results, Service, and Configuration work areas, to move to (open) a different work area.

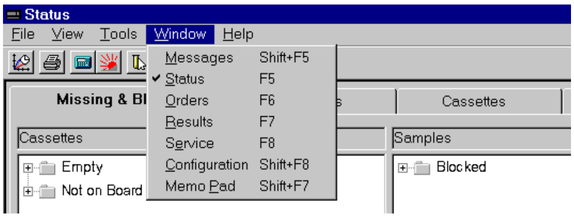
► To open a different work area from the menu bar

1 Click Window on the menu bar.

The Window menu is displayed.

The current work area is marked with ✓.

2 Click the required work area name.


Status
File View Tools Window Help
Messages Shift+F5
✓ Status F5
Orders F6
Results F7
Service F8
Configuration Shift+F8
Memo Pad Shift+F7
Missing & Bl
Cassettes
Cassettes
Empty
Not on Board
Samples
Blocked

Tabs

In the Status, Orders, Results, and Service work areas, the information is arranged in several tabs. The tabs of a work area contain different but related information.

► To open a different tab

Click a tab,

or

1 Press the Tab key until the work area tab has focus.

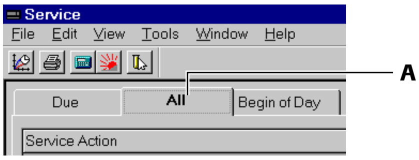
You see a dotted line around the tab.

2 Press the Right Arrow key to move left-to-right from tab to tab.

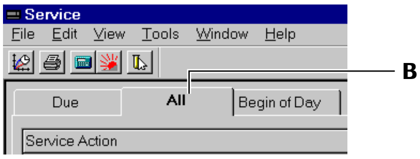
3 Press the Left Arrow key to move right-to-left.

Tips

- In Windows, focus is the place where the next command you make has its effect. When a tab (or a button) has focus in Windows, the tab (or button) is displayed with a dotted box (A) around it.


Service
File Edit View Tools Window Help
A
Due
All
Begin of Day
Service Action

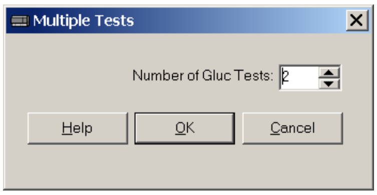
- If the All tab (A) has focus, pressing the Right or Left Arrow key moves the focus to the next tab.
- If the All tab does not have focus (B), pressing the Arrow keys moves focus to other items inside the tab.


Service
File Edit View Tools Window Help
B
Due
All
Begin of Day
Service Action

Dialog boxes

Dialog boxes are secondary windows that are displayed on top of the main work area window. Typically, a dialog box requests or provides information that is supplementary to that in the main window.

You can access dialog boxes from within the work areas or through the menu bar. Some dialog boxes are shared by different work areas.


Multiple Tests
Help
OK
Cancel

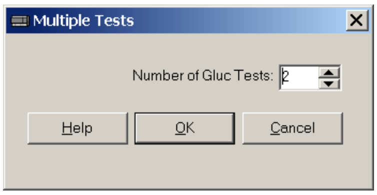
Number of Gluc Tests: 2

Working with the user interface

The user interface contains many functions that are familiar to Windows users and a few that are unique to this interface.

Command buttons

Click a command button to perform a particular function. For example, click OK to request the specified number of tests.


Multiple Tests
Help
OK
Cancel

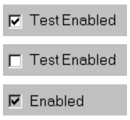
Number of Gluc Tests: 2

Check boxes

1. Click once on a check box to select the suggested value.
2. Click again to clear the check box.

   A grayed check box, with or without a tick, shows a preselected value, which you cannot change.

   Typically, this means that the values have been set in other dialog boxes or have been preset on your system. It may also mean that you do not have sufficient user privileges to alter this box.



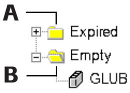
☑ Test Enabled
☐ Test Enabled
☑ Enabled

Tip

You can select more than one check box at the same time, in the same window.

Folders

1. Double-click a closed folder (A) to open it to show its contents.
2. Double-click an open folder (B) to close it.


A
B
Expired
Empty
GLUB

Tip

You can also single-click ⊞ to open the folder and single-click ⊟ to close it.

Drop down lists

1. Click the Down Arrow to expand a drop down list.
2. Select an item from the list.

Cassette & Interval
None
Interval
Cass-Lot & Interval
Cassette & Interval

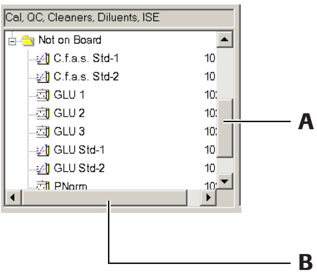
Context menus

“Context menus (right mouse button)” on page A-53

Scroll bars

Use the scroll bars when the list is longer than the available space.

Click and hold the scroll bar, and then move the mouse up or down on a vertical scroll bar (A) or left or right on a horizontal scroll bar (B).

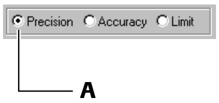

Cal, QC, Cleaners, Diluents, ISE
Not on Board
C.f.a.s. Std-1
C.f.a.s. Std-2
GLU 1
GLU 2
GLU 3
GLU Std-1
GLU Std-2
PNorm
A
B

Tip

You can use the Arrow keys and the Page Up and Page Down keys instead of the mouse.

Option buttons

1. Click the required option (A) to select it.
2. Clear the option, by selecting one of the other options.



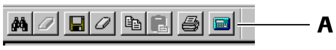
● Precision ○ Accuracy ○ Limit

Tip

Options in the same frame (the rectangular box around the options) are mutually exclusive. Options in other frames are treated separately.

Toolbars

Click a toolbar button to quickly start specific functions. The content of the toolbar (A) depends on which work area is displayed.



This is what the toolbar buttons do:

Button	Function	Button	Function
💾	Archive Definitions: archive current definitions and system settings. You can then reload them in the event of a system failure.	🗎	Detail: display a Detail dialog box about the currently selected item.
💾	Load Definitions: load archived definitions.	🔍	Find: find an order ID
🖩	Calculator: open the calculator tool.	📋	Paste: copy details from a previously saved order into the current order.
✐	Clear: clear the current order. If the order has not previously been saved, all details are lost.	🖶	Print: Print the current screen.
⎘	Copy: copy details of the current order into memory so that you can retrieve them into another order later on.	💾	Save: save the current order (Orders work area).
📈	Test Calibrations: Show the test calibrations.	✸	Begin of Day: Start the Begin of Day actions manually.
⇱	Place Items: Display the Place Items dialog box.	▥	Barcode: Display the Barcode dialog box.

Tip

If a function is not currently available, the corresponding toolbar button is grayed out.

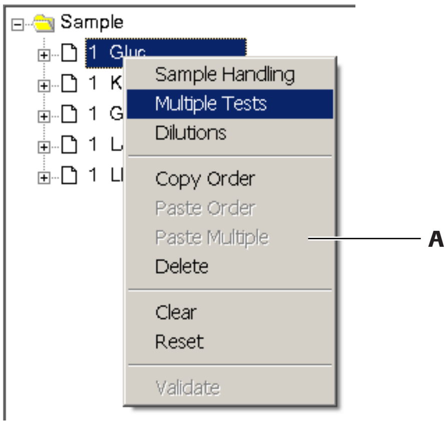
Tips and techniques

Here are a few suggestions that may help speed up your work.

Context menus (right mouse button)

Use the right mouse button to display a context menu (A) for the currently selected item. The context menu contains a list of frequently used commands relevant to the item you have selected.

This is almost always quicker than using the menu bar, because you do not have to search the menus.



► To display a context menu

1 Select the item you are interested in.

2 Place the cursor over the item and click the right-hand mouse button.

The context menu is displayed.

Tip

Context menus are not available for all items, but they are useful for some key actions that you have to perform frequently, or simply to see what actions can be executed on the selected item.

Windows shortcut keys

You can often use the standard Windows functions cut, paste, and copy text, for example, in the Memo Pad. These functions have the same shortcut keys that you find on any PC:

Use Ctrl + C to copy, Ctrl + X to cut, and Ctrl + V to paste.

If you are not familiar with Windows, you use Ctrl + C, for example, as follows:

1 Select text or an item.
2 Press and hold down the Ctrl key.
3 Press and release the C key.
4 Release the Ctrl key.

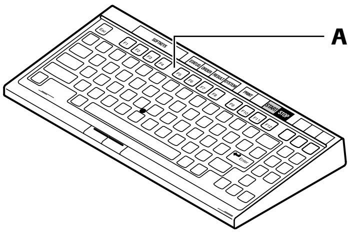
The selected text or item is copied to the clipboard (part of Windows). You can retrieve it into another document later by using the Paste function.

Tips

- The Windows Paste function is not quite the same as the *Cedex Bio HT* paste function, but the general idea is the same.
- There are two Ctrl keys, one each side of the space bar. They both perform the same function.
- The cut function copies text or an item to the clipboard and deletes the original.

Function keys

The function keys (A) are located on the top row of the keyboard.



Key	Function
F5	Go to the Status work area.
F6	Go to the Orders work area.
F7	Go to the Results work area.
F8	Go to the Service work area.

"Work areas" on page A-49

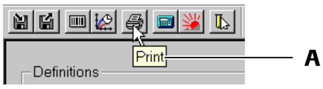
Tooltips

Tooltips provide prompts to help you when you are not familiar with the user interface, or when you are using a feature for the first time.

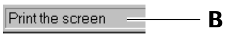
► To view a tooltip

1 Place the cursor over an item and hold it there for a couple of seconds.

The corresponding tooltip (A) is displayed.



2 Check the status bar (B) for an expansion of the tooltip.



Tip

If you are not familiar with the user interface, use the tooltip function to find out what each button in the navigation bar does.

Drag and drop

Use this technique, for example, to place items on a rack.

1 Move the cursor over the item you want to place.

2 Press the left mouse button and hold it down.

3 Move the mouse so that the item is dragged across the screen.

4 When your item reaches the required destination, release the mouse button.

Online Help

Displaying context-sensitive and general Help from the system

This chapter describes the Help system for the *Cedex Bio HT* analyzer. It explains how to use context-sensitive links, how to access general Help, and how to access additional information in Acrobat format.

Note: Help facilities and content are subject to change within a software release. Please check the current Help for details.

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Help window A-56
Finding information A-60
Context Help A-63
    Displaying context Help A-63
    Context Help window A-63
General Help A-64
    Displaying general Help A-64
Message Help A-65
    System messages A-65
    Controller messages A-66
Related topics A-67
Glossary A-68

Introduction

The *Cedex Bio HT* analyzer has a comprehensive Windows Help system that provides information to help you to:

- Perform the most common tasks in your daily work.
- Understand the content of each work area, tab, and dialog box as you are using them.
- Perform tasks associated with running the instrument.
- Perform service actions and other routine manual tasks using step-by-step instructions.
- Understand and take action on messages generated by the system.

You can also use the Help to:

- Display general information about work areas, tabs, and dialog boxes.
- Look up the definition of any term or component by using the glossary.
- Access documents online in Acrobat format for additional information.

Types of online information

There are three types of online information on the *Cedex Bio HT* analyzer:

- Context (or context-sensitive) Help is standard Windows Help that explains the currently displayed work area, dialog box, or message. You can display context Help directly from the current window or dialog box.
- General Help is standard Windows Help that explains more about the function of the different work areas, tabs, and dialog boxes. It also provides relevant background information to concepts and tasks. You display general Help from the Help menu in the user interface.
- Message Help works similar to the context Help. It provides more detailed information on messages that are currently displayed by the system, and gives hints or instructions towards the resolution of the problem described in the message.
- Online books are documents presented in Acrobat format.

Starting and closing online Help

► To display online Help information

- Press F1 on the keyboard.

or

- Click Help on the currently displayed dialog box.

or

- Choose Help on the menu bar of the currently displayed dialog box, and then choose the appropriate option.

► To close online Help and return to the application interface

- Click Close on the button bar of the Help window.

or

- Choose File > Exit in the Help window.

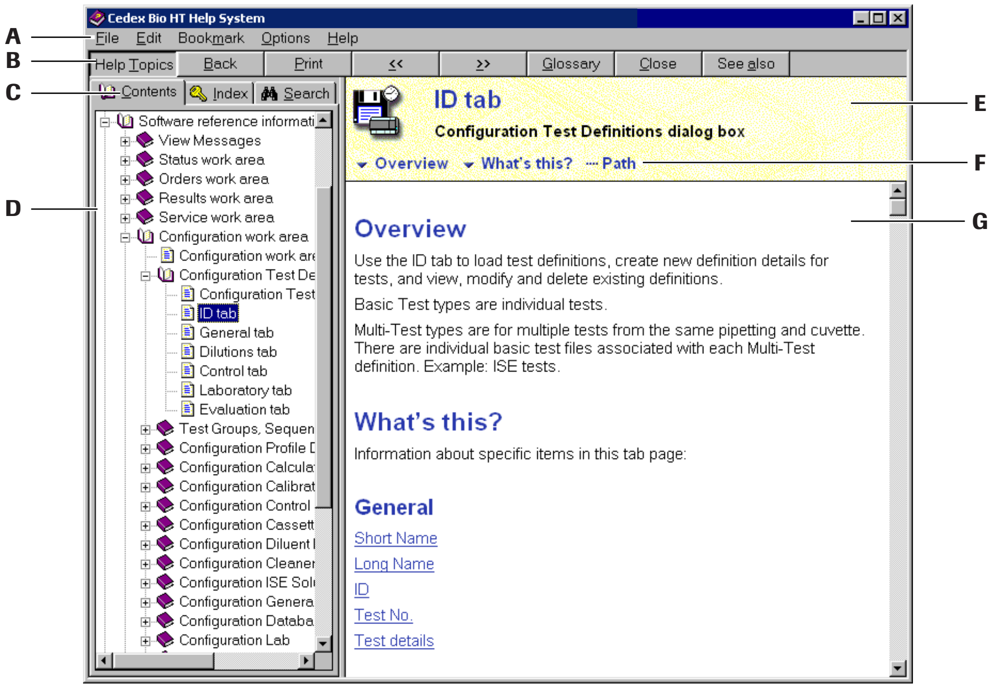
Help window

In Windows XP, the Help screen is available in English only.

The Help window is divided into the header, navigation pane, and topic area.

- The header contains the menu and button bars, which provide access to standard Windows Help functions.
- The navigation pane consists of three tabs, each providing a specific way of finding information in the Help.
- The topic area displays the information contained in a Help topic.

The following figure shows an example of a context Help topic:


A
B
C
D
E
F
G
Cedex Bio HT Help System
File Edit Bookmark Options Help
Help Topics Back Print << >> Glossary Close See also
Contents Index Search
Software reference informati
View Messages
Status work area
Orders work area
Results work area
Service work area
Configuration work area
Configuration work are
Configuration Test De
Configuration Test
ID tab
General tab
Dilutions tab
Control tab
Laboratory tab
Evaluation tab
Test Groups, Sequen
Configuration Profile D
Configuration Calcula
Configuration Calibrat
Configuration Control
Configuration Cassett
Configuration Diluent I
Configuration Cleaner
Configuration ISE Solu
Configuration Genera
Configuration Databa
Configuration Lab
Overview What's this? Path
Short Name
Long Name
ID
Test No.
Test details

ID tab

Configuration Test Definitions dialog box

Overview

Use the ID tab to load test definitions, create new definition details for tests, and view, modify and delete existing definitions.

Basic Test types are individual tests.

Multi-Test types are for multiple tests from the same pipetting and cuvette. There are individual basic test files associated with each Multi-Test definition. Example: ISE tests.

What's this?

Information about specific items in this tab page:

General

A *Menu bar - contains the standard Windows Help menus.*

B *Button bar - contains buttons for the Help window. The actual buttons displayed may be different to those shown here.*

C *Tabs in the navigation pane - provide different ways of accessing Help topics. See "Finding information" on page A-62.*

D *Navigation pane - click Help Topics in the button bar to show or hide this pane.*

E *Banner bar - this part of the topic area remains static and visible when you scroll up and down the Help topic.*

F *Click an item to jump to a subsection of the topic.*

G *This part of the topic area contains the actual information of the topic.*

Menu bar

Use the menu bar to access Help functions. For example, you can:

- Specify whether the Help window stays on top of the main program window.
- Create a bookmark in the Help, so that you can quickly return to a topic later.
- Add an annotation (to a Help topic) to allow other users to read when they open the Help.

Banner bar

In topics such as reference information of dialog boxes or tabs, clicking buttons in the banner bar takes you to the corresponding subsections of the topic. In general Help topics, clicking Top in the banner bar brings you back to the beginning of the current topic.

Button bar

Use the buttons on the button bar to display other topics within the Help system. The following buttons are available in a window:

Click this button...	In order to...
Help Topics	• Hide the navigation pane to work with the full screen topic area, to make space for large graphics, for example. • Display the navigation pane when working with the full screen topic area.
Back	Go back to the Help topic you displayed before the current topic. Click repeatedly to go back several steps.
Print	Print the current topic.
<<	Browse backwards. (Go to the preceding topic in the Help file.)
>>	Browse forward. (Go to the next topic in the Help file.)
Glossary	Display the glossary.
See Also	Display a list of shortcuts to important related topics. This button is only active if there is at least one such shortcut on the current topic.
Close	Close the Help window.

Navigation aids

Different icons, buttons, and text formats assist you in moving around topics:

(For moving to different topics, see also “Button bar” on page A-59.)

Click this...	In order to...
▼ or the following blue text	Jump to a subsection of the topic.
▶ or the following blue text	Jump to another topic.
····	Display path information in a pop-up window. You find this button in the banner bar of context Help topics.
◀ or the following blue text	Go back to the parent topic, to which the current topic provides additional information.
Sample pop-up	Display information on this word or expression in a pop-up window.
Blue text	In running text, jump to another topic or to a subsection of the topic.
⤒	Go back to the beginning of a topic.
[See also]	Display a list of the most important related topics. This button is only active if there is at least one such shortcut on the current topic.

Tips

- Click [>>] or [<<] on the button bar to browse through Help information and thus gain an overview on a particular subject.
- Some general Help topics provide at the beginning a list of subsections of the topic. Click ▼ or its associated text to jump to subsections. Clicking ⤒ in the banner bar brings you back to the beginning of the current topic. To find a different subsection of the topic, select another list element.
- In topics such as reference information on dialog boxes or tabs, click the banner bar buttons to jump to subsections of the current topic.
- In workflow topics, click a number symbol ② in the banner bar to jump to the corresponding step.

Navigation pane

For Help topics with large graphics, such as the service action topics, you can hide the navigation pane so that you can see the whole graphic.

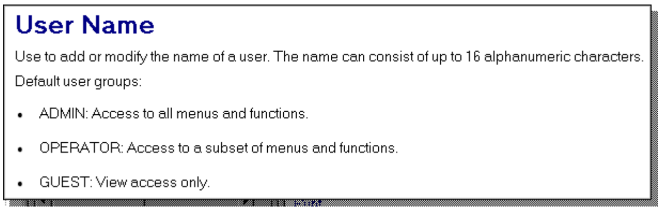
Click Help Topics to hide and redisplay the navigation pane.

The navigation pane is divided into the Contents, Index, and Search tabs, each providing a different method of searching and accessing Help topics.

Pop-up window

You open a pop-up window either by clicking underlined blue text or by clicking ···· in the banner bar of a context Help window.

The pop-up window remains open until you close it by clicking anywhere in the Help window. Only one pop-up window is displayed at a time.



User Name

Use to add or modify the name of a user. The name can consist of up to 16 alphanumeric characters.

Default user groups:

- ADMIN: Access to all menus and functions.
- OPERATOR: Access to a subset of menus and functions.
- GUEST: View access only.

Some practical hints

- Click Help Topics to expand the topic area to the full width of the Help window.

  Click Help Topics again to redisplay the navigation pane.
- Right-click in the topic area to display a context menu with options that lead to useful functions such as
  - Adjusting the display font size.
  - Defining whether the Help window should always remain visible on your screen.
  - Printing the contents of the topic.
- Choose Options > Display History Window to display a window that contains the topic titles of the topics you previously visited.

  Double-click a title to redisplay the topic.

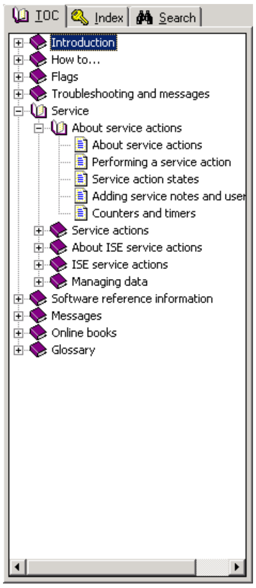
Finding information

Use the tabs in the navigation pane to access Help information in the way that suits you best. In addition, you can click buttons in the button bar to find related topics and to browse through topics.

The following sections describe these various methods.

Contents tab

The Contents tab displays the Help contents in a directory tree. Click ⊞ to open a book and display its content; click ⊟ to close the book. Click an entry to display the content of the topic in the topic area.



TOC | Index | Search

- Introduction
- How to...
- Flags
- Troubleshooting and messages
- Service
  - About service actions
    - About service actions
    - Performing a service action
    - Service action states
    - Adding service notes and user
    - Counters and timers
  - Service actions
  - About ISE service actions
  - ISE service actions
  - Managing data
- Software reference information
- Messages
- Online books
- Glossary

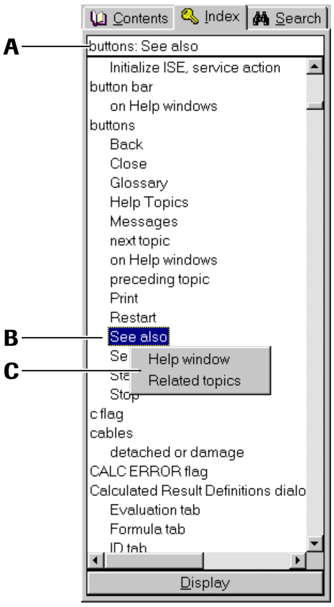
Index tab

The Index tab displays the index entries (each topic may have multiple entries).

► To find a topic with the help of the index

1. Click the Index tab.
2. In the text box (A), type the first few characters of a keyword you associate with the information you are looking for.
3. Select an item from the list (B) to display the topic in the topic area.

   If there is more than one topic for this item, a list is displayed. Select one topic from the list (C) to display it in the topic area.


Contents
Index
Search
A
buttons: See also
Initialize ISE, service action
button bar
on Help windows
buttons
Back
Close
Glossary
Help Topics
Messages
next topic
on Help windows
preceding topic
Print
Restart
B
See also
C
Help window
Related topics
c flag
cables
detached or damage
CALC ERROR flag
Calculated Result Definitions dialo
Evaluation tab
Formula tab
ID tab
Display

Tip

To select all existing text in the box, click and then right-click in the box (A), and choose Select All from the context menu.

Search tab

The Search function lists all occurrences of a particular word.

This is useful if you do not know the topic heading or if your Index search was not successful. The first time you use the search facility, the system has to build the word list. Follow the online instructions to create the list and then type the word on which you want to find Help information.

► To find the topic that contains a certain word

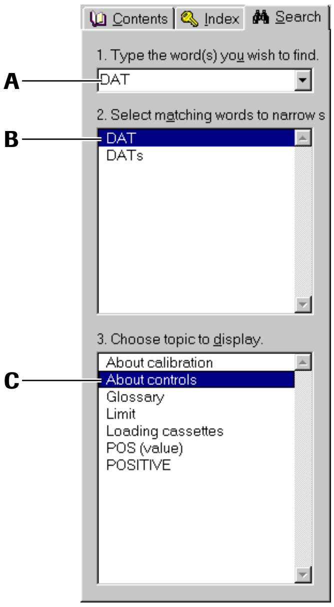
1 Click the Search tab.

2 Type the first few letters of the word into text box 1 (A).

3 Select a matching word from box 2 (B).

4 Select the topic you want to display from the list in box 3 (C).

The information is displayed in the topic area.



1. Type the word(s) you wish to find.

DAT

2. Select matching words to narrow s

DAT
DATs

3. Choose topic to display.

About calibration
About controls
Glossary
Limit
Loading cassettes
POS (value)
POSITIVE

Browsing

Help information is thematically grouped together. Browsing through the topics is a good way of getting a quick overview on the subject you are interested in.

► To browse

Click >> or << on the button bar to browse through Help information.

Context Help

Context Help is always specific to the particular area that currently has focus, that is, the object that your next click or key press will act upon. On the *Cedex Bio HT* analyzer, context Help is generally displayed in a Help window rather than a pop-up window.

Displaying context Help

Which context Help topic is displayed, depends on the object that has focus when you press F1.

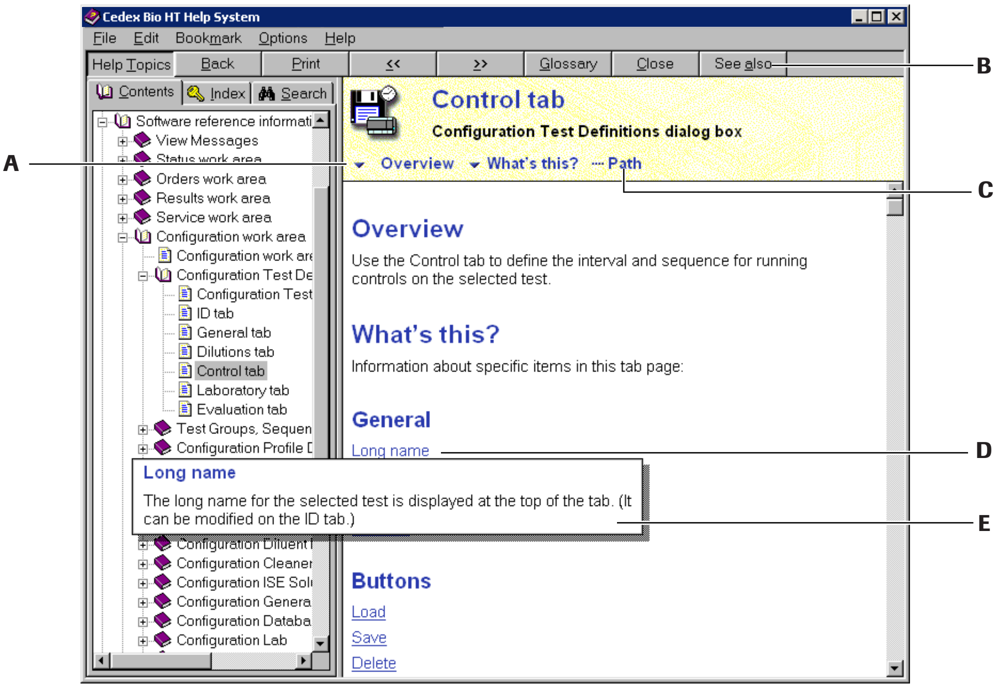
To display context Help, check which type of object currently has focus:

- On a tab, ensure the focus is on the tab (click the tab) and then press F1 on the keyboard.
- In a dialog box, click the Help button (if available) or press F1.
- In a message box, click the Help on Message button, if available. Pressing F1 displays the main Help window.

"Message Help" on page A-68

Context Help window

The figure below shows a typical context Help window.


Cedex Bio HT Help System
File Edit Bookmark Options Help
Help Topics Back Print << >> Glossary Close See also
Contents Index Search
Software reference informati
View Messages
Status work area
Orders work area
Results work area
Service work area
Configuration work area
Configuration work are
Configuration Test De
Configuration Test
ID tab
General tab
Dilutions tab
Control tab
Laboratory tab
Evaluation tab
Test Groups, Sequen
Configuration Profile D
Configuration Diluent
Configuration Cleaner
Configuration ISE Solu
Configuration Genera
Configuration Databa
Configuration Lab
Overview What's this? Path
A
B
C
D
E

Control tab

Configuration Test Definitions dialog box

Overview

Use the Control tab to define the interval and sequence for running controls on the selected test.

What's this?

Information about specific items in this tab page:

General

Long name

Long name

The long name for the selected test is displayed at the top of the tab. (It can be modified on the ID tab.)

Buttons

Load

Save

Delete

A *Banner bar - click an item to jump to a particular section within the current Help topic.*

B *Click See also to display a list of shortcuts to important related topics. (This button is only active if there is at least one such shortcut reference on the current topic.)*

C *Click Path to display, in a pop-up window, the navigation path that leads to the dialog box for which the current Help information is displayed.*

D *Help hotspot - click the underlined blue text to display, in a pop-up window, information on the selected item.*

E *Pop-up window that is displayed when you click the Help hotspot.*

General Help

General Help provides additional information that is not available in the context Help. It contains more detailed information about tabs and background information, including “About...” topics and step-by-step instructions for user tasks.

General Help gives you access to the following types of information:

- General information about some aspects of the system or its operation. This includes essential safety information.
- How to... information providing step-by-step instructions for performing tasks.
- Information on flags.
- Troubleshooting information and explanations on messages.
- Guidance on software supported service actions.
- Work area reference information providing information about specific tabs and dialog boxes within the user interface.
- Glossary

“Glossary” on page A-71

Displaying general Help

You can access general Help information either from the menu bar in a main work area or from any Help window.

- From a main work area, choose Help > General Help in the menu bar to display the default Help topic.
- From any Help window, use the Contents, Index, or Search tab to access general Help topics.

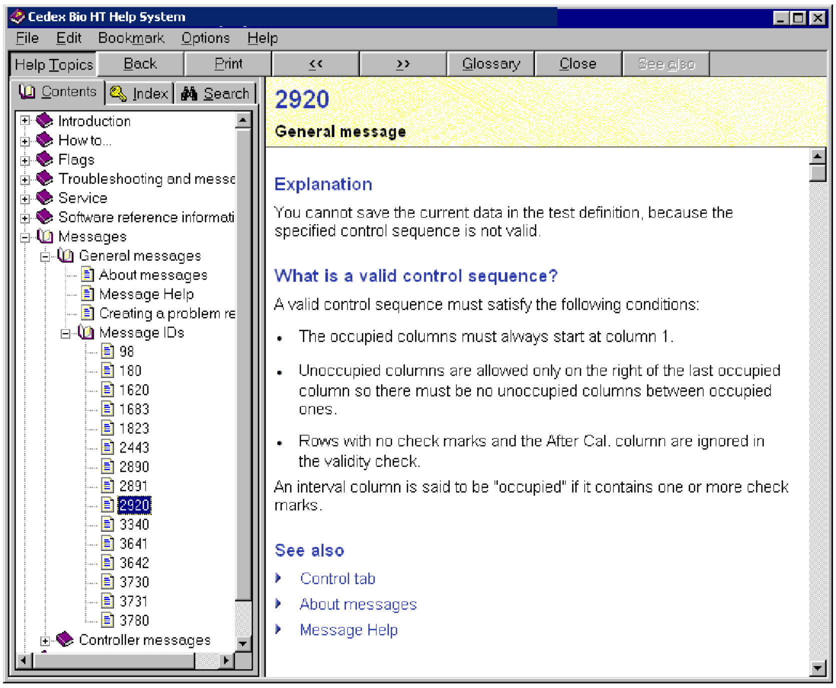
“Finding information” on page A-62

Message Help

You can access the Help system from a message dialog box.

System messages

You can display Help on a system message by clicking the Help On Message button in the message dialog box. (Some messages do not have a Help On Message button.)


Cedex Bio HT Help System
File
Edit
Bookmark
Options
Help
Help Topics
Back
Print
<<
>>
Glossary
Close
See also
Contents
Index
Search
Introduction
How to...
Flags
Troubleshooting and messe
Service
Software reference informati
Messages
General messages
About messages
Message Help
Creating a problem re
Message IDs
98
180
1620
1683
1823
2443
2890
2891
2920
3340
3641
3642
3730
3731
3780
Controller messages

2920

General message

Explanation

You cannot save the current data in the test definition, because the specified control sequence is not valid.

What is a valid control sequence?

A valid control sequence must satisfy the following conditions:

- The occupied columns must always start at column 1.
- Unoccupied columns are allowed only on the right of the last occupied column so there must be no unoccupied columns between occupied ones.
- Rows with no check marks and the After Cal. column are ignored in the validity check.

An interval column is said to be "occupied" if it contains one or more check marks.

See also

- Control tab
- About messages
- Message Help

You can also look up messages that have been generated by the system in the View Messages dialog box.

Chapter 15, “Messages”

► To find Help on a particular message

1 Press F1 or click Help to open the Help system.

2 Click the Search tab in the navigation pane.

3 In text box 1, type the whole or part of the message number.

4 If necessary, narrow your search by selecting an item from box 2.

5 Select the required message in box 3.

For details on using the search facility, see “Search tab” on page A-63.

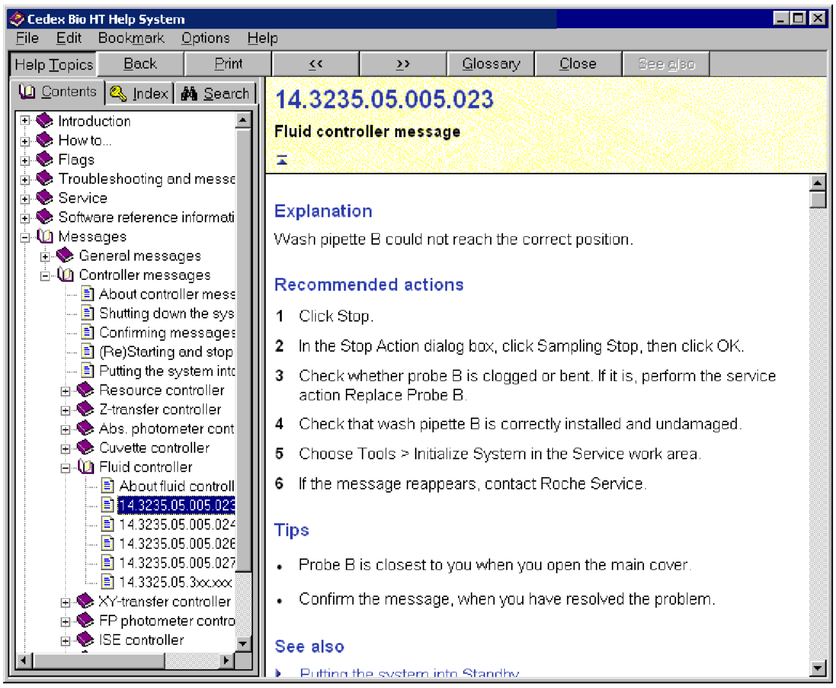
Tip

Step 3 - You can also type any word or phrase that identifies the message.

Controller messages

Warnings from the controller boards generate messages from which you can display Help.

Click Help On Message in the message dialog box to display Help on a controller message.


Cedex Bio HT Help System
File
Edit
Bookmark
Options
Help
Help Topics
Back
Print
<<
>>
Glossary
Close
See also
Contents
Index
Search
Introduction
How to...
Flags
Troubleshooting and messa
Service
Software reference informati
Messages
General messages
Controller messages
About controller mess
Shutting down the sys
Confirming messages
(Re)Starting and stop
Putting the system intc
Resource controller
Z-transfer controller
Abs. photometer cont
Cuvette controller
Fluid controller
About fluid controll
14.3235.05.005.023
14.3235.05.005.024
14.3235.05.005.026
14.3235.05.005.027
14.3325.05.3xx.xxx
XY-transfer controller
FP photometer contro
ISE controller

14.3235.05.005.023

Fluid controller message

Explanation

Wash pipette B could not reach the correct position.

Recommended actions

1 Click Stop.

2 In the Stop Action dialog box, click Sampling Stop, then click OK.

3 Check whether probe B is clogged or bent. If it is, perform the service action Replace Probe B.

4 Check that wash pipette B is correctly installed and undamaged.

5 Choose Tools > Initialize System in the Service work area.

6 If the message reappears, contact Roche Service.

Tips

- Probe B is closest to you when you open the main cover.
- Confirm the message, when you have resolved the problem.

See also

Putting the system into Standby

Related topics

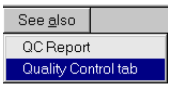
In many topics, especially with context-sensitive information, you can click the See also button in the button bar to display a list of shortcuts to important related topics.

This button is only active if there is at least one such shortcut on the current topic.

► To display related topics

1 Click See also on the button bar.

A list of headings of important related topics is displayed.

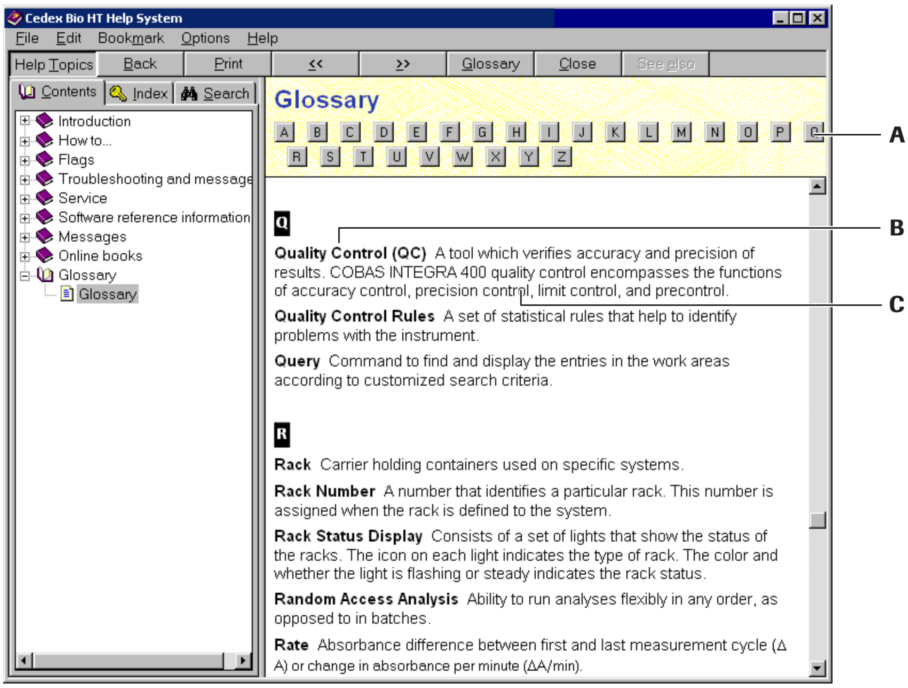


2 Select one heading from the list.

The topic with this heading is displayed.

Glossary

You can access the glossary from the button bar of any main Help window. Use the letter buttons or scroll bar to move down the glossary.


Cedex Bio HT Help System
File Edit Bookmark Options Help
Help Topics Back Print << >> Glossary Close See also
Contents Index Search
Introduction
How to...
Flags
Troubleshooting and message
Service
Software reference information
Messages
Online books
Glossary
Glossary
A B C D E F G H I J K L M N O P Q
R S T U V W X Y Z
A
B
C

Glossary

Q

Quality Control (QC) A tool which verifies accuracy and precision of results. COBAS INTEGRA 400 quality control encompasses the functions of accuracy control, precision control, limit control, and precontrol.

Quality Control Rules A set of statistical rules that help to identify problems with the instrument.

Query Command to find and display the entries in the work areas according to customized search criteria.

R

Rack Carrier holding containers used on specific systems.

Rack Number A number that identifies a particular rack. This number is assigned when the rack is defined to the system.

Rack Status Display Consists of a set of lights that show the status of the racks. The icon on each light indicates the type of rack. The color and whether the light is flashing or steady indicates the rack status.

Random Access Analysis Ability to run analyses flexibly in any order, as opposed to in batches.

Rate Absorbance difference between first and last measurement cycle (Δ A) or change in absorbance per minute (ΔA/min).

A *Letter buttons - Click to jump to the items beginning with this letter.*

B *Glossary term.*

C *Definition of the term.*

Operation B

Part B gives you a detailed description of the user interface and how you use it in your everyday tasks. It provides sample daily workflows and step-by-step information about common procedures that you need to perform as part of your daily workflow. It also provides information about results on samples, calibrations, and controls.

Daily workflow

Use the system efficiently

This chapter provides step by step instructions for the daily workflow. The daily routines are described for three typical laboratory setups: working *without* sample barcodes and *without* a host system, working *with* sample barcodes and *without* a host system, and working *with* sample barcodes and *with* a host system.

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  Safety precautions B-5
  Working with a host computer B-6
  Assumptions B-6
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  Logging on and checking the Memo Pad B-8
  Checking the Begin of Day report B-8
  Loading cleaners, diluents, and ISE solutions B-9
  Loading and mixing cassettes B-9
  Checking resources B-10
  Performing service actions B-11
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Introduction

This chapter guides you through your working day. The optimized workflow makes sure that you get the most out of the *Cedex Bio HT* features.

The workflow is divided into the following three sections:

Daily start-up	Prepare your system for the day.
Daily routine	Keep your system running for the routine work.
End of day	Prepare your system for the next day.

The Daily routine tasks are further divided into three procedures, reflecting the three main kinds of laboratory setup.

Sample barcode	Host	See subsection…
✗	✗	"Daily routine (without sample barcode and without host)" on page B-12.
✓	✗	"Daily routine (with sample barcode and without host)" on page B-17.
✓	✓	"Daily routine (with sample barcode and with host)" on page B-22.

To provide you with a clear overview of the procedures, the level of detail with which individual steps are described is kept low. More complex steps are described in detail later in the manual, and cross references are provided where appropriate. Alternatively, you can find detailed descriptions of the steps in the Online Help.

Safety precautions

Follow these safety precautions at all times while using the instrument.

Caution

- *Never open the instrument cover while the instrument is running.*
- *Never remove a rack from the rack area if the rack status indicators are red.*
- *Never touch any moving parts.*
- *Never place any objects (bottles, samples, etc.) on top of the instrument.*
- *Follow the instrument messages (View Messages).*
- *Perform maintenance as required.*
- *Remove the side panels only when the power supply is disconnected.*
- *Use the Cedex Bio HT analyzer only for determination of analytes in aqueous solutions.*

Also, follow the general safety precautions described on page ix.

Working with a host computer

To allow efficient processing of the large quantities of test data generated by the *Cedex Bio HT* system, a host computer may be installed. This host computer, while optional, is recommended for most of the *Cedex Bio HT* applications. Communication between the host system and the *Cedex Bio HT* system is provided by the *Cedex Bio HT* host interface.

The *Cedex Bio HT* host interface is hardware and software allowing communication between the *Cedex Bio HT* data station and the host computer.

Communication between the host and the *Cedex Bio HT* data station works on a master-slave basis, where the host is the master. This allows the host to send orders to the instrument via the data station as well as to request results from the data station. The data station, being slave, never sends data to the host unless the host first requests it.

Features of the host interface include:

Orders	• Entry • Modification • Deletion • Host query
Results	• Single results • Collated results

Host software, including the host user interface, is not supplied by Roche and is thus customer specific. For information about the data display at your host or about the method of communication between host and data station including data formats, please refer to the Host Interface Manual.

For a description of routine operation using a host computer, see

"Daily routine (with sample barcode and with host)" on page B-22

Assumptions

The *Cedex Bio HT* system can be set up in different ways to accommodate the way you work in your laboratory. The workflows outlined in this user documentation assumes that your system is configured and used in one of the following recommended ways:

Daily startup

Cassettes	Cassettes stay on board during the night.
System shutdown	The system is not shut down during the night.

Daily routine

Working without barcode and without host

Sample barcode	To work without barcode on sample tubes, clear the Use Barcode On Sample Cups check box in Configuration / General / Barcode.
Rack position	To automatically assign samples to rack positions, select the Automatically Assign Rack Positions check box in Configuration / Database / Automatic Actions.

To reset rack position at Begin of Day, select the Reset Rack Positions at Begin of Day check box in Configuration / Database / Automatic Actions.

Rack configuration The rack configuration depends on the number of different tube types and sample types used in your laboratory.

- If you use only one tube type and one sample type, use tube type racks.
- If you use more than one tube type and more than one sample type, use tube type racks for the most often used tube and sample types and use sample type racks for infrequently used tube and sample types.

Working with barcode and without host

Rack position The system identifies the samples by their barcode. Therefore, the function Automatically Assign Rack Positions is not used.

- Clear the Automatically Assign Rack Positions check box in Configuration / Database / Automatic Actions.
- Select the Reset Rack Positions at Begin of Day check box in Configuration / Database / Automatic Actions.

Sample barcode To work with barcode on sample tubes, select the Use Barcode On Sample Cups check box in Configuration / General / Barcode.

Rack configuration The rack configuration depends on the information coded in the sample barcode.

- If your sample barcode includes sample type information, use tube type racks.
- If your sample barcode does not include sample type information, use sample type racks.

Working with barcode and with host

Rack position The system identifies the samples by their barcode. Therefore, the function Automatically Assign Rack Positions is not used.

- Clear the Automatically Assign Rack Positions check box in Configuration / Database / Automatic Actions.
- Select the Reset Rack Positions at Begin of Day check box in Configuration / Database / Automatic Actions.

Sample barcode To work with barcode on sample tubes, select the Use Barcode On Sample Cups check box in Configuration / General / Barcode.

Rack configuration The rack configuration depends on the information coded in the sample barcode.

- If your sample barcode includes sample type information, use tube type racks.
- If your sample barcode does not include sample type information, use sample type racks.

Daily start-up

Prepare your system for the day

❶ Logging on and checking the Memo Pad

► To log on

1. Press Shift + F3.
2. Type your user ID and password.
3. Click Log On.

“Logging onto the system” on page B-33

► To check the Memo Pad

1. Click Memo Pad on the navigation bar.
2. Check the Memo Pad for messages. A red icon points to an urgent message.

“Checking the Memo Pad” on page B-51

❷ Checking the Begin of Day report

The system performs preselected service actions and other automatic actions at the assigned Begin of Day (BOD) time. No user action is required.

The Begin of Day report summarizes all information about the last performed BOD. Use the report to plan your next steps, such as preparing calibrators and controls, loading cassettes, or performing service actions that are due.

► To check the Begin of Day report

1. Choose File > Print Report > Begin of Day.
2. Click OK.

   The Begin of Day report is printed.
3. Check the Begin of Day report for the following items and plan your next steps accordingly.
   - Service actions that need to be performed.
   - Required calibrators, controls, cleaners, diluents, and ISE fluids. (Only cassettes required for tests remain on board.)
   - Cassettes that need to be handled.

Tips

- To identify the required calibrators, check also the status of the calibration intervals on the Test Calibrations dialog box (Tools > Test Calibrations).
- Prepare calibrators and controls now, so that they are ready for loading later on.
- If no BOD was performed, choose Tools > Execute Begin of Day or click to start BOD manually.

“Printing the Begin of Day report” on page B-52

③ Loading cleaners, diluents, and ISE solutions

► To load cleaners, diluents, and ISE solutions

1. Check the printed Begin of Day report for cleaner, diluent, and ISE solutions to be loaded.
2. Load the cleaner and diluents on their correct rack positions indicated in the Begin of Day report.
3. Insert the racks.

Tip

After loading or replacing ISE solutions on the ISE rack, the ISE Rack Replaced dialog box is displayed. On the dialog box select the ISE solutions that you have replaced. *Leave the check boxes cleared for ISE solutions you have not replaced.*

"Replacing the cleaner" on page B-43
"Replace ISE solutions on the ISE rack" on page F-32

④ Loading and mixing cassettes

► To load cassettes on board

1. Click the Cassettes tab in the Status work area to check what cassettes you need to load for the daily routine. Check the printed Begin of Day report for additional cassettes to be loaded.
2. Unwrap the cassettes and pierce the aluminum foil on the bottles containing lyophilized or granulate reagents, using the tip of the unlock rack tool.
3. Place the required cassettes on a cassette rack.
4. Insert the rack into a free slot in the cassette area.

"Loading cassettes" on page B-40

Tip

- Each cassette is automatically checked for correct filling when it is placed for the first time on the instrument. If the integrated cassette volume check fails a message is displayed and the cassette access is denied. Use another cassette if the volume check fails.

Warning

Do not interchange cassettes among different Cedex Bio HT systems and instruments. Each cassette rack with its cassettes may be used on one individual Cedex Bio HT instrument only. Each cassette has its own individual cassette number, which the instrument uses to identify it. Using a cassette already used on a different Cedex Bio HT instrument may lead to incorrect results.

If more than one Cedex Bio HT instrument is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual instrument (e.g. by color coding).

► To mix cassettes

1. Click the New Messages tab in the Messages work area to check for messages of the format "Cassette <name> on rack <number>, Position <position> requires mixing".
2. Click the Cassettes tab in the Status work area and check for cassettes with the Req.

Mixing status.

3. Wait until the rack status light is green and remove the racks containing the cassettes to be mixed.
4. Place the reconstituted cassettes on an external mixer for 10 minutes.

   Place the cassettes needing periodical mixing on an external mixer for one minute.
5. Re-insert the rack into the cassette area.
6. After the required mixing time is elapsed, remove the rack again and put the reconstituted cassettes on the rack.
7. Re-insert the rack into the cassette area.

⑤ Checking resources

The background color of the Status button tells you whether you need to take action or not.

Button	Background color	Take action...
	Red (Fatal error)	Immediately
	Yellow	Soon (when convenient)
	Green or gray	None

The icon on the Status button also changes, depending on the resource status. For example, if cuvettes are running low, you see the cuvette icon (on a yellow background).

Status Button	Resource	User action
	Cleaner	Replace cleaner.
	Cuvettes	Add cuvettes to cuvette reservoir.
	Water	Check water supply connections. If supplied from an external reservoir, check the level.
	Cuvette Waste	Empty the cuvette waste reservoir.
	Waste Drain	If waste is put into an external reservoir, check the level.
	Temperature	Check all ventilation filters and passages. Check the fuses.
	ISE Solutions	Check the ISE tab in the Status work area for more information.

Tip

You can check all system resources on the Analyzer tab of the Status work area.

“Checking resources” on page B-42

⑥ Performing service actions

► To perform service actions

1. Check the printed Begin of Day report for service actions that need to be performed. Prepare all required tools and materials.
2. Click Service on the navigation bar.
3. Select the required service actions from the Due tab.
4. Click Perform.
5. Perform the service actions according to the on-screen instructions. Click Help for full details.

Tip

Should you choose to not perform the Backup database service action automatically at BOD (Service > View Counters / Service Intervals), then if the Backup database service action is due, perform it at the end of the day. This service action may take about 5 minutes.

Caution

Database backup must be performed in regular intervals otherwise the accumulated data will fill all available space on the hard disk and the system will be blocked.

Chapter 14, "Service actions"

Chapter 13, "Service action software"

⑦ Loading calibrators and controls

► To load calibrators and controls on board

1. Check the printed Begin of Day report for the preassigned rack numbers and positions of the required calibrators and controls.
2. Load the calibrators and controls on their correct rack positions.
3. Insert the rack into a free slot in the sample or cassette area.

Tips

- Calibrations are performed automatically together with the next ordered test.
- Automatic calibrations are only performed, if a test is requested during the day. If applicable, request a calibration manually in Orders / Calibration.
- The preferred slot for calibrators and controls is slot I, which is in the cooled cassette area.
- You must put multi-set calibrators in continuous positions on the same rack, starting with the highest concentration standard furthest away from you when you insert the rack.
- If barcodes for calibrators with several standards are used, label all standard cups with the same barcode.

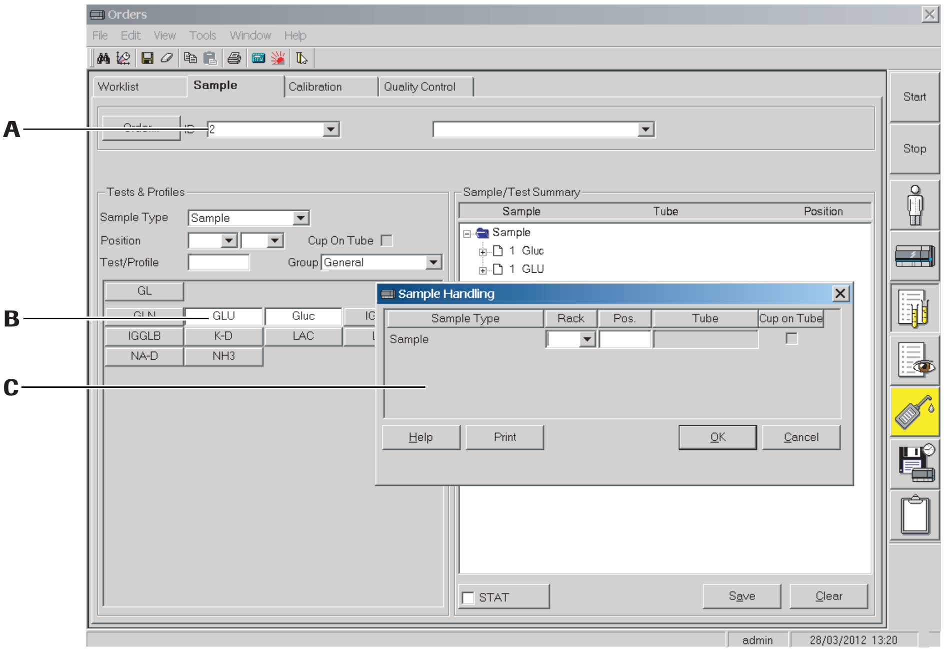
"Loading calibrators, controls, and diluents" on page B-40

Daily routine (without sample barcode and without host)

Keep your system running

❶ Creating orders

Create an order in three steps:


A
B
C
Orders
File Edit View Tools Window Help
Worklist
Sample
Calibration
Quality Control
Order
ID 2
Tests & Profiles
Sample Type Sample
Position
Cup On Tube
Test/Profile
Group General
GL
GLN
GLU
Gluc
IGGLB
K-D
LAC
NA-D
NH3
Sample/Test Summary
Sample
Tube
Position
Sample
1 Gluc
1 GLU
Sample Handling
Sample Type
Rack
Pos.
Tube
Cup on Tube
Sample
Help
Print
OK
Cancel
STAT
Save
Clear
Start
Stop
admin
28/03/2012 13:20

A *Enter an order ID and if required a comment.*

B *Select tests and click Save.*

C *To confirm rack number and position for all sample types on the Sample Handling dialog box, click OK.*

"Creating an order" on page B-95

► To add the order ID

Type an order number in the Order ID box and press Enter.

Tip

Type * (asterisk) in the Order ID box and press Enter to use the lookup function. The Lookup dialog box is displayed with a list of all order IDs stored on the system.

"Specifying an order ID" on page B-95

► To select tests and save the order

1 Click the buttons for the required profiles and tests.

2 Click STAT for a high priority order.

3 Click Save.

Tips

- The samples are automatically assigned to appropriate rack positions. These positions can be modified, if required, on the Sample Handling dialog box, which is displayed after the order is saved.
- By default, the sample type Automatic is displayed. The Position boxes for rack number and position are disabled.
- Change the test group in the Group box to limit or expand the display of test and profile buttons. Select General to display all available test and profile buttons.

If you want...	**Then do this**...
To limit or expand the display of test and profile buttons in the Test & Profiles group	Select the appropriate Group in the Test & Profiles group.
To delete a test from the Sample, Calibration, or QC tab	Right-click the test in the Test Summary group, and choose Delete from the context menu. Alternatively, click the test button.
To request a dilution for a sample test	Right-click the test in the Sample / Test Summary group, and choose Dilutions from the context menu. Select or type a factor in the Dilutions dialog box.
To add a sample test several times to an order	Right-click the test in the Sample / Test Summary group, and choose Multiple Tests from the context menu. Type the number of tests in the Multiple Tests dialog box.
To create multiple copies of an order	Right-click in the Sample / Test Summary group, and choose Copy Order from the context menu. Right-click again in the Test Summary group, and choose Paste Multiple from the context menu. Type the number of orders you wish to create, and accept or change the first order ID for the new orders.

► To confirm rack positions

1. Check the automatically assigned rack number and position for each sample type listed on the Sample Handling dialog box. Modify the position if required.
2. Select the Cup on Tube check box if the sample is placed in a secondary cup on a primary tube.
3. Click OK.

Tips

- The Sample Handling dialog box is displayed when you click Save.
- When a sample type is used for the first time on a day, you must assign it manually to the appropriate rack position, using the Sample Handling dialog box. Afterwards, all other rack position assignments are done automatically by the system.
- Enter the rack number and position for samples manually on the Sample Handling dialog box, if the function Automatically Assign Rack Positions is not used.
- The Cup on Tube function on the Sample Handling dialog box is only available, if the selected rack has the appropriate tube type assigned to it, the rack position is entered, and the rack is not on board.

"Assigning samples to racks" on page B-96
"Selecting Cup on Tube" on page B-100

② Loading samples on board

► To load samples on board

1 Choose File > Print Report > Loadlist from the menu bar and click OK to print the loadlist.

2 Use the loadlist to place the sample tubes and cups on the correct rack position.

3 Insert the rack into one of the slots in the sample area.

Tips

- Cup on Tube samples are not displayed in the list.
- You can use only one tube type per rack.
- If you use tubes that are not defined on your system, you may damage the probes.
- Before you move a rack, wait until the status light above the rack is green.

"Loading samples" on page B-38

③ Start processing

► To start processing

- If the system is in Standby, press F11 or click Start on the navigation bar.
- If the system is in Sleeping, press F11 or click Start on the navigation bar.

  As soon as the system is in Standby, press F11 again.

Tip

If you work with Auto Start (Configuration / General / System), the system starts processing automatically, as soon as you insert a rack, provided there are orders that need to be processed.

► To check the worklist

1 Click Orders on the navigation bar and click the Worklist tab.

2 Check the Worklist for orders that are blocked or have no samples on board.

3 Take the appropriate actions to resolve the problem.

4 If you are sure all your scheduled orders are being processed properly and your first results are calculated, switch to the Validate tab in the Results work area for result validation.

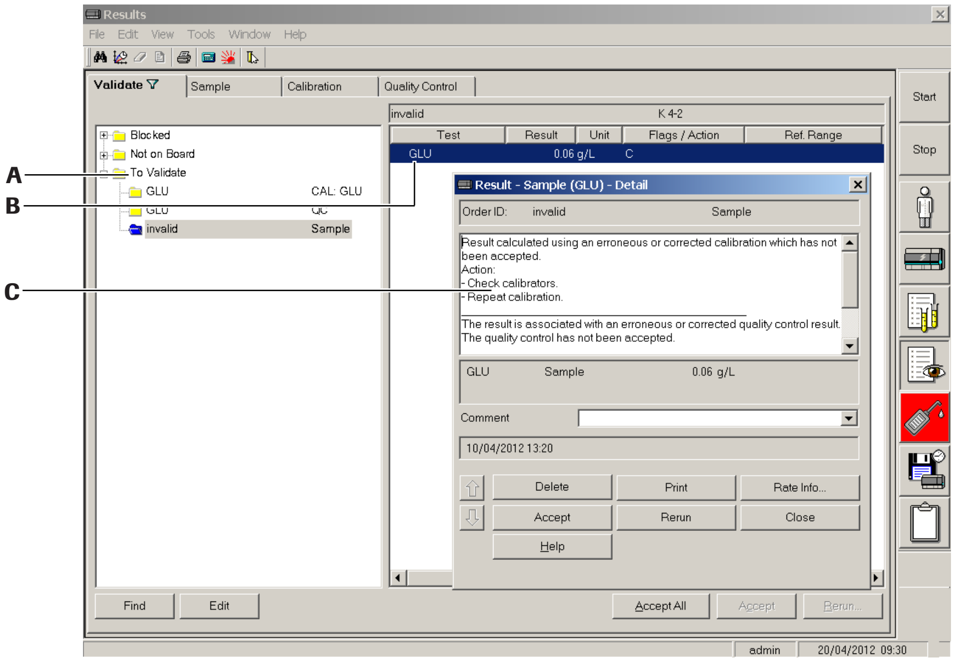
Tips

- Select a blocked test and press F1 to get Help.
- Select an order and click Edit to modify the order or click Validate to switch to the Validate tab in the Results work area for result validation.

"Worklist tab" on page B-89
"Printing the Worklist" on page B-56

❹ Validating results

Validate results on the Validate tab of the Results work area.


A
B
C
Results
File Edit View Tools Window Help
Validate
Sample
Calibration
Quality Control
Blocked
Not on Board
To Validate
GLU CAL: GLU
GLU QC
invalid Sample
invalid K 4-2
Test Result Unit Flags / Action Ref. Range
GLU 0.06 g/L C
Result - Sample (GLU) - Detail
Comment
Delete Print Rate Info...
Accept Rerun Close
Help
Find Edit
Accept All Accept Rerun...
Start
Stop
admin 20/04/2012 09:30

Order ID: invalid Sample

Result calculated using an erroneous or corrected calibration which has not been accepted.
Action:
- Check calibrators.
- Repeat calibration.

The result is associated with an erroneous or corrected quality control result.
The quality control has not been accepted.

GLU Sample 0.06 g/L

10/04/2012 13:20

A *Check all results located in the To Validate folder on the Validate tab of the Results work area.*

B *Double-click a result line in the list of results.*

The Result Detail dialog box is displayed, where you get information about recommended actions for flagged results.

C *Perform the recommended actions for flagged results.*

Recommended actions include:

- *Rerun the test with dilution or concentration.*
- *Repeat the test.*
- *Check the required items as listed in the recommended actions of the Results Detail dialog box.*
- *Review test result details.*
- *Accept the result.*

“Validate tab” on page B-117
“Working with results” on page B-128

► To rerun or repeat a test

1. Click the Validate tab on the Results work area.
2. In the To Validate folder, select a sample, calibration, or control order.
3. Select the result in question from the Results list, and click Rerun.

   The Dilutions dialog box is displayed if you have selected a test order.
4. Do one of the following:
   - Select a dilution factor to rerun the test order with dilution.
   - Select As Original to repeat the test order with the setting defined in the test definition.

“Requesting a dilution” on page B-107

► To review test result details

1. Click the Validate tab on the Results work area.
2. In the To Validate folder, select a sample, calibration, or control order.
3. Double-click a result line in the list of results.

   The Result Detail dialog box is displayed.
4. Click Rate Info.

   The Rate Info dialog box is displayed.
5. Review the information to check the reason for the flag.

Tips

- Select an order and click Edit to switch to the Orders work area for editing.
- Right-click an order in the Blocked folder and choose Detail from the context menu to see the test status of the blocked order on the Results - Detail - Test Orders dialog box.

► To accept a result

1. Click the Validate tab on the Results work area.
2. In the To Validate folder, select a sample, calibration, or control order.
3. Select a result from the list of results and click Accept.

Tips

- Click Accept All to accept all the results of the selected order.
- Set the filter option of the Validate tab to Unaccepted to display only the unaccepted results of the selected order.

⑤ Printing the Final Report

► To print the Final Report

1. Choose File > Print Report > Final Report from the menu bar.

   The Print Result Query dialog box is displayed.
2. Define the ranges for Order ID and Order Date.
3. Click Print.

Tip

Select Final Report in Configuration / Database / Automatic Actions to print the Final Report automatically as soon as the last result of an order is accepted.

“Printing the Final Report” on page B-53

Daily routine (with sample barcode and without host)

Keep your system running

❶ Loading samples on board

► To load samples on board

1. Place the sample tubes and cups on the appropriate racks.
2. Insert the rack into one of the slots in the sample area.

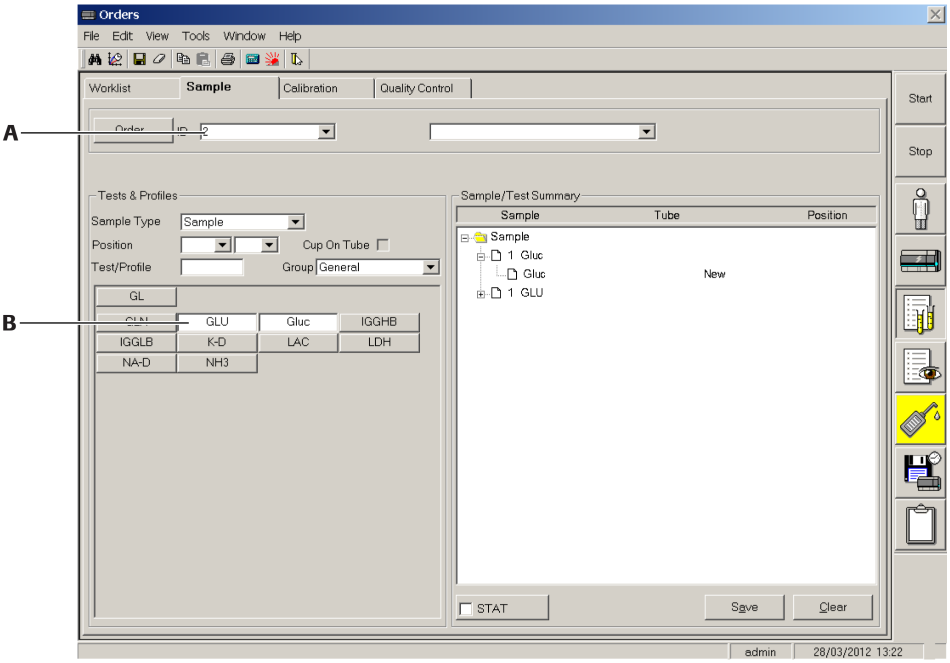
Tips

- You can use only one tube type per rack.
- If you use tubes that are not defined on your system, you may damage the probes.
- Before you move a rack, wait until the status light above the rack is green.

"Loading samples" on page B-38

❷ Creating orders

Create an order in three steps:


A
B
Orders
File Edit View Tools Window Help
Worklist
Sample
Calibration
Quality Control
Order
ID
Start
Stop
Tests & Profiles
Sample Type
Sample
Position
Cup On Tube
Test/Profile
Group
General
GL
GLN
GLU
Gluc
IGGHB
IGGLB
K-D
LAC
LDH
NA-D
NH3
Sample/Test Summary
Sample
Tube
Position
Sample
1 Gluc
Gluc
New
1 GLU
STAT
Save
Clear
admin
28/03/2012 13:22

A *Select an order ID from the list.*

B *Select tests and click Save.*

"Creating an order" on page B-95

► To select the order ID

Select the appropriate order ID from the Order ID list and press Enter.

Tips

- The Order ID list lists all samples that are present on the system and have no orders assigned to them.
- Type * (asterisk) in the Order ID box and press Enter to use the lookup function. The Lookup dialog box is displayed with a list of all order IDs stored on the system.

👁 *"Specifying an order ID" on page B-95*

► To select tests and save the order

1 Click the buttons for the required profiles and tests.
2 Click STAT for a high priority order.
3 Click Save.

Tip

Change the test group in the Group box to limit or expand the display of test and profile buttons. Select General to display all available test and profile buttons.

👁 *"Selecting tests for the order" on page B-96*

If you want...	Then do this...
To limit or expand the display of test and profile buttons in the Test & Profiles group	Select the appropriate Group in the Test & Profiles group.
To delete a test from the Sample, Calibration, or QC tab	Right-click the test in the Test Summary group, and choose Delete from the context menu. Alternatively, click the test button of the test.
To request a dilution for a sample test	Right-click the test in the Sample / Test Summary group, and choose Dilutions from the context menu. Select or type a factor in the Dilutions dialog box.
To add a sample test several times to an order	Right-click the test in the Sample / Test Summary group, and choose Multiple Tests from the context menu. Type the number of test in the Multiple Tests dialog box.
To create multiple copies of an order	Right-click in the Sample / Test Summary group, and choose Copy Order from the context menu. Right-click again in the Test Summary group, and choose Paste Multiple from the context menu. Type the number of orders you wish to create, and accept or change the first order ID for the new orders.

③ Confirming the orders

► To print the worklist

1 Choose File > Print Report > Worklist from the menu bar and click OK to print the worklist.

2 Review the printed worklist to confirm that all orders have been entered correctly.

“Printing the Worklist” on page B-56

④ Start processing

► To start processing

- If the system is in Standby, press F11 or click Start on the navigation bar.
- If the system is in Sleeping, press F11 or click Start on the navigation bar.

  As soon as the system is in Standby, press F11 again.

Tip

If you work with Auto Start (Configuration / General / System), the system starts processing automatically, as soon as you insert a rack, provided there are orders that need to be processed.

► To check the worklist

1. Click Orders on the navigation bar and click the Worklist tab.
2. Check the Worklist for orders that are blocked or have no samples on board and for samples that have no orders assigned to them.
3. Take the appropriate actions to resolve the problem.
4. If you are sure all your scheduled orders are being processed properly and your first results are calculated, switch to the Validate tab in the Results work area for result validation.

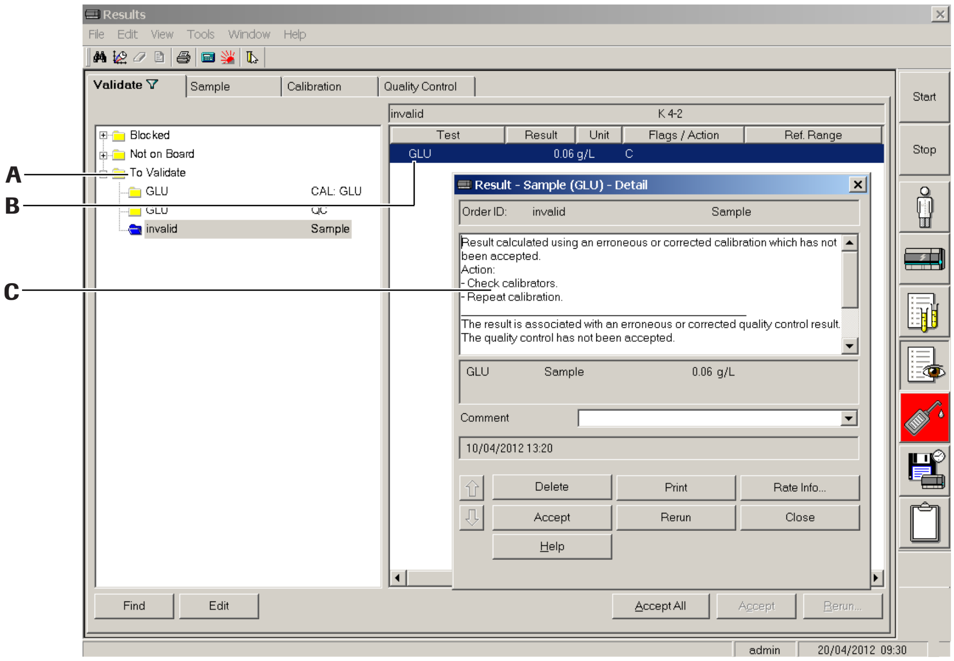
Tips

- Select a blocked test and press F1 to get Help.
- Select an order and click Edit to modify the order or click Validate to switch to the Validate tab in the Results work area for result validation.

“Worklist tab” on page B-89

❺ Validating results

Validate results on the Validate tab of the Results work area.


Results
File Edit View Tools Window Help
Validate
Sample
Calibration
Quality Control
Blocked
Not on Board
To Validate
GLU CAL: GLU
GLU QC
invalid Sample
invalid K 4-2
Test Result Unit Flags / Action Ref. Range
GLU 0.06 g/L C
Result - Sample (GLU) - Detail
Comment
Delete Print Rate Info...
Accept Rerun Close
Help
Find Edit
Accept All Accept Rerun...
Start
Stop
admin 20/04/2012 09:30
A
B
C

Order ID: invalid Sample

Result calculated using an erroneous or corrected calibration which has not been accepted.
Action:
- Check calibrators.
- Repeat calibration.

The result is associated with an erroneous or corrected quality control result.
The quality control has not been accepted.

GLU Sample 0.06 g/L

10/04/2012 13:20

A *Check all results located in the To Validate folder on the Validate tab of the Results work area.*

B *Double-click a result line in the list of results.*

The Result Detail dialog box is displayed, where you get information about recommended actions for flagged results.

C *Perform the recommended actions for flagged results.*

Recommended actions include:

- *Rerun the test with dilution or concentration.*
- *Repeat the test.*
- *Check the required items as listed in the recommended actions of the Results Detail dialog box.*
- *Review test result details.*
- *Accept the result.*

“Validate tab” on page B-117
“About results” on page B-112

► To rerun or repeat a test

1. Click the Validate tab on the Results work area.
2. In the To Validate folder, select a sample, calibration, or control order.
3. Select the result in question from the list of results and click Rerun.

   The Dilutions dialog box is displayed if you have selected a test order.
4. Do one of the following:
   - Select a dilution factor to rerun the test order with dilution.
   - Select As Original to repeat the test order with the setting defined in the test definition.

“Requesting a dilution” on page B-107

► To review test result details

1. Click the Validate tab on the Results work area.
2. In the To Validate folder, select a sample, calibration, or control order.
3. Double-click a result line in the list of results.

   The Result Detail dialog box is displayed.
4. Click Rate Info.

   The Rate Info dialog box is displayed.
5. Review the information to check the reason for the flag.

Tips

- Select an order and click Edit to switch to the Orders work area for editing.
- Right-click an order in the Blocked folder and choose Detail from the context menu to see the test status of the blocked order on the Results - Detail - Test Orders dialog box.

► To accept a result

1. Click the Validate tab on the Results work area.
2. In the To Validate folder, select a sample, calibration, or control order.
3. Select a result from the list of results and click Accept.

Tips

- Click Accept All to accept all the results of the selected order.
- Set the filter option of the Validate tab to Unaccepted to display only the unaccepted results of the selected order.

⑥ Printing the Final Report

► To print the Final Report

1. Choose File > Print Report > Final Report from the menu bar.

   The Print Result Query dialog box is displayed.
2. Define the ranges for Order ID and Order Date.
3. Click Print.

Tip

Select Final Report in Configuration / Database / Automatic Actions to print the Final Report automatically as soon as the last result of an order is accepted.

"Printing the Final Report" on page B-53

Daily routine (with sample barcode and with host)

Keep your system running

❶ Loading samples on board

► To load samples on board

1. Place the sample tubes and cups on the appropriate racks.
2. Insert the rack into one of the slots in the sample area.

Tips

- You can use only one tube type per rack.
- If you use tubes that are not defined on your system, you may damage the probes.
- Before you move a rack, wait until the status light above the rack is green.

👁 *"Loading samples" on page B-38*

❷ Start processing

► To start processing

- If the system is in Standby, press F11 or click Start on the navigation bar.
- If the system is in Sleeping, press F11 or click Start on the navigation bar.

  As soon as the system is in Standby, press F11 again.

Tip

If you work with Auto Start (Configuration / General / System), the system starts processing automatically, as soon as you insert a rack, provided there are orders that need to be processed.

❸ Monitoring scheduled orders

► To identify blocked tests or samples that are not on board

1. Check the Validate tab on the Results work area for orders that are blocked or have no samples on board.
2. Double-click a sample, calibration, or control order in the folders Blocked or Not On Board.

   The Results - Detail - Test Orders dialog box is displayed.
3. On the Results - Detail - Test Orders dialog box, select a blocked test and press F1 to get Help.
4. Take the appropriate actions to resolve the problem.

Tips

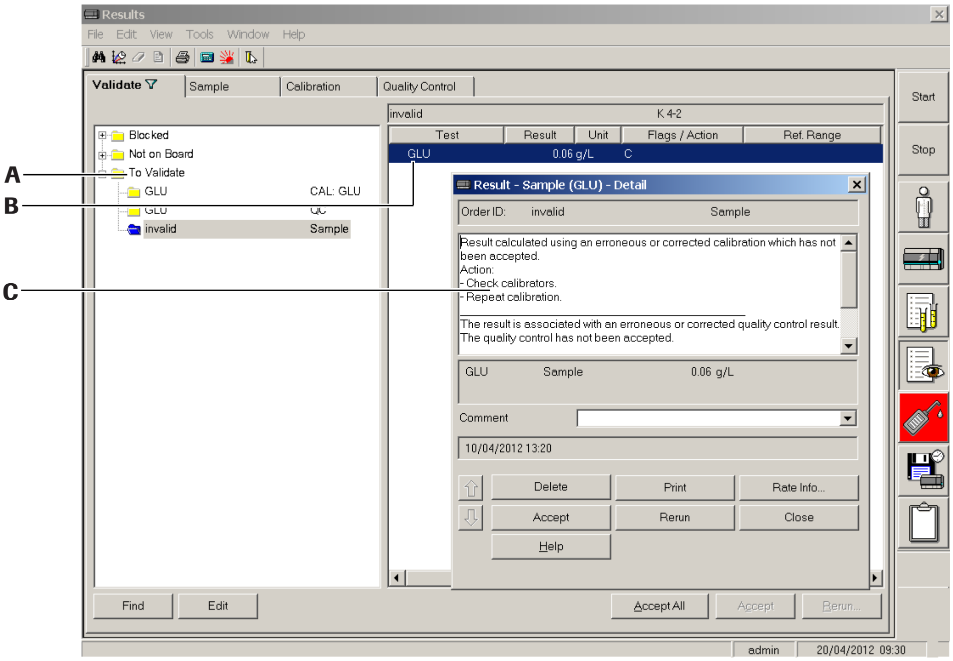
- The folders Blocked and Not On Board are only listed on the Validate tab, if they contain at least one entry. If the folders are not displayed, no tests are blocked and all samples are on board.

- Right-click an order in the Blocked folder and choose Detail from the context menu to see the test status of the blocked order on the Results - Detail - Test Orders dialog box.
- Select an order and click Edit to switch to the Orders work area for editing.

"Validate tab" on page B-117

④ Validating results

Validate results on the Validate tab of the Results work area.


A
B
C
Results
File Edit View Tools Window Help
Validate
Sample
Calibration
Quality Control
Blocked
Not on Board
To Validate
GLU CAL: GLU
GLU QC
invalid Sample
invalid K 4-2
Test Result Unit Flags / Action Ref. Range
GLU 0.06 g/L C
Result - Sample (GLU) - Detail
Order ID: invalid Sample
GLU Sample 0.06 g/L
Comment
10/04/2012 13:20
Delete
Print
Rate Info...
Accept
Rerun
Close
Help
Find
Edit
Accept All
Accept
Rerun...
Start
Stop
admin
20/04/2012 09:30

Result calculated using an erroneous or corrected calibration which has not been accepted.
Action:
- Check calibrators.
- Repeat calibration.

The result is associated with an erroneous or corrected quality control result.
The quality control has not been accepted.

A *Check all results located in the To Validate folder on the Validate tab of the Results work area.*

B *Double-click a result line in the list of results.*

The Result Detail dialog box is displayed, where you get information about recommended actions for flagged results.

C *Perform the recommended actions for flagged results.*

Recommended actions include:

- *Rerun the test with dilution or concentration.*
- *Repeat the test.*
- *Check the required items as listed in the recommended actions of the Results Detail dialog box.*
- *Review test result details.*
- *Accept the result.*

"Validate tab" on page B-117
"About results" on page B-112

► To rerun or repeat a test

1. Click the Validate tab on the Results work area.
2. In the To Validate folder, select a sample, calibration, or control order.
3. Select the result in question from the list of results and click Rerun.

   The Dilutions dialog box is displayed if you have selected a test order.

4 Do one of the following:
  - Select a dilution factor to rerun the test order with dilution.
  - Select As Original to repeat the test order with the setting defined in the test definition.

“Requesting a dilution” on page B-107

► To review test result details

1 Click the Validate tab on the Results work area.
2 In the To Validate folder, select a sample, calibration, or control order.
3 Double-click a result line in the list of results.
The Result Detail dialog box is displayed.
4 Click Rate Info.
The Rate Info dialog box is displayed.
5 Review the information to check the reason for the flag.

► To accept a result

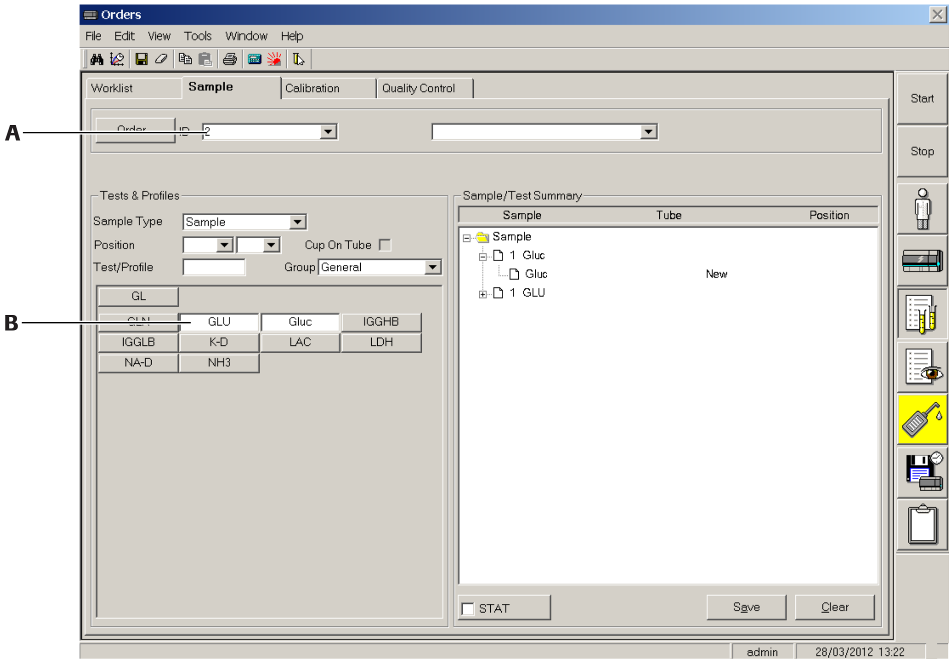
1 Click the Validate tab on the Results work area.
2 In the To Validate folder, select a sample, calibration, or control order.
3 Select a result from the list of results and click Accept.

Tips

- Click Accept All to accept all the results of the selected order.
- Set the filter option on the Validate tab to Unaccepted to display only the unaccepted results of the selected order.

⑤ Creating orders

If necessary, create orders manually in three steps:


A
B
Orders
File Edit View Tools Window Help
Worklist
Sample
Calibration
Quality Control
Order ID
Start
Stop
Tests & Profiles
Sample Type Sample
Position
Cup On Tube
Test/Profile
Group General
GL
GLN
GLU
Gluc
IGGHB
IGGLB
K-D
LAC
LDH
NA-D
NH3
Sample/Test Summary
Sample
Tube
Position
Sample
1 Gluc
Gluc
New
1 GLU
STAT
Save
Clear
admin
28/03/2012 13:22

A *Add order ID on the Sample tab of the Orders work area.*

B *Select tests and click Save.*

"Creating an order" on page B-95

► To select the order ID

1 Select the appropriate order ID from the Order ID list and press Enter.

2 Depending on the configuration of your system, add additional order information:

- In the text box to the right of the order ID, type the text, or select a predefined text from the list, and press Enter.

Tips

- The Order ID list lists all samples that are present on the system and have no orders assigned to them.
- Type * (asterisk) in the Order ID box and press Enter to use the lookup function. The Lookup dialog box is displayed with a list of all order IDs stored on the system.

"Specifying an order ID" on page B-95

► To select tests and save the order

1 Click the buttons for the required profiles and tests.

2 Click STAT for a high priority order.

3 Click Save.

Tip

Change the test group in the Group box to limit or expand the display of test and profile buttons. Select General to display all available test and profile buttons.

“Selecting tests for the order” on page B-96

If you want…	**Then do this…**
To limit or expand the display of test and profile buttons in the Test & Profiles group	Select the appropriate Group in the Test & Profiles group.
To delete a test from the Sample, Calibration, or QC tab	Right-click the test in the Test Summary group, and choose Delete from the context menu.
To request a dilution for a sample test	Right-click the test in the Sample / Test Summary group, and choose Dilutions from the context menu. Select or type a factor in the Dilutions dialog box.
To add a sample test several times to an order	Right-click the test in the Sample / Test Summary group, and choose Multiple Tests from the context menu. Type the number of test in the Multiple Tests dialog box.
To create multiple copies of an order	Right-click in the Sample / Test Summary group, and choose Copy Order from the context menu. Right-click again in the Test Summary group, and choose Paste Multiple from the context menu. Type the number of orders you wish to create, and accept or change the first order ID for the new orders.

End of day

① Removing sample racks

► To remove sample racks

1. Open the rack access panel.
2. Remove all sample racks.

② Deleting results and orders

Caution

Do not delete the results of the day if you archive the results on the system.

► To delete selected results

1. Click Results on the navigation bar.
2. Click the Sample tab.
3. Right-click the date folder you want to delete and choose Delete from the context menu.
4. Click Yes to confirm the deletion.

Tip

To delete a single result, right-click a result in the Results list, and choose Delete from the context menu.

"Purging results" on page B-130

► To purge orders

1. Choose Tools > Purge Orders.
2. Click Yes on the Confirm Purge Orders dialog box.

Tips

- Depending on the setup of your system, orders are deleted automatically at BOD time.
- If you archive the results in the results work area you need to purge the results regularly. The *Cedex Bio HT* analyzer is not designed to store large quantities of results on the system. As part of data management, you should periodically purge results manually. At least every 2 months is recommended.

"Purging and deleting orders" on page B-60

❸ Complete the remaining service actions

► To complete the remaining service actions

1. Click Service on the navigation bar.
2. Select the required service actions from the Due tab.
3. Click Perform.
4. Perform the service actions according to the on-screen instructions. Click Help for full details.

Chapter 14, "Service actions"
Chapter 13, "Service action software"

❹ Logging off

► To log off

1. Double-click the user ID in the status bar.
2. Click Log Off.

"Logging off and shutting down the system" on page B-35
"Logging off the system" on page B-35
"Shutting down the system" on page B-35

Routine tasks

Performing everyday tasks to keep the system running

This chapter describes the routine tasks that you need to perform to keep your instrument running.

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Starting up and logging on to the system

The following procedures apply to the hardware configuration of Cedex Bio HT analyzer only.

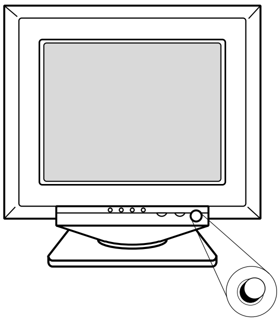
Switching on the system

Always switch on the system components in the following order:

1. Monitor
2. Printer
3. Instrument
4. Computer

Switching on the monitor

The monitor On/Off switch is situated at the bottom right on the front of the monitor:



► To switch on the monitor

Press the switch.

The green indicator on the left lights up, indicating that the monitor is on.

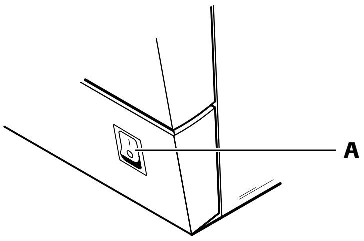
Switching on the printer

Standard printers go into Standby mode as soon as they are connected to the mains power.

If there is an On/Off switch on your printer, switch on the printer and follow your printer instructions.

Switching on the instrument

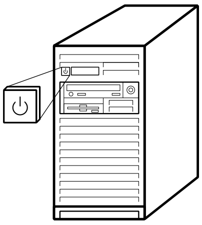
To turn on the instrument, press the main switch (A).



Switching on the computer

► To switch on the computer

Press the On/Off switch of the computer. The green indicator lights up as soon as the computer starts up and the first text row is displayed on the monitor screen. The computer gives an audible signal.



After completing the startup procedures, the user interface of the *Cedex Bio HT* software is displayed. Startup may take a few minutes.

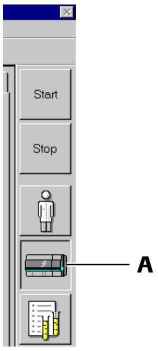
Caution

Do not switch off the computer if the user interface is not displayed on the screen after a few minutes. The computer may be recovering the database (for example, after a power failure). Switching off the computer could cause loss of data.

Starting the instrument

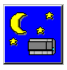
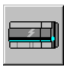
The method of starting up the instrument depends on its state when you start work. The Status button (A) on the navigation bar shows the instrument state.

"System states" on page A-42



► To start up the instrument

Use the following table to decide which start-up procedure to use.

State	Button		Start-up procedure
Power off: instrument is turned off.			Power on the instrument then the computer. The system performs a full initialization.
Sleeping: instrument has not been used for a while.		Blue background	Press F11 on the keyboard or click Start on the navigation bar to start a partial instrument initialization.
Standby: instrument was started by an earlier user.		Gray background	None. You are ready to log on.

Initialization

After starting up from power off:

1. The system goes through its Windows XP start-up procedure.
2. The Windows Desktop is displayed.
3. The *Cedex Bio HT* main window is displayed showing the Status work area.
4. The Status button on the navigation bar shows the system is initializing (flashing arrow).
5. The system goes into Standby.

Tips

- You must log on before you can access all the functions available to you.
- If you switch on after the Begin of Day (BOD) time has passed, all the BOD actions are run automatically before processing orders, provided you had not switched on the system previously that day.
- The system goes into Standby after a definable period of inactivity (default value is 10 minutes), or at a defined time. Then, after a defined interval (by default, “Sleeping Mode after” is set to 10 minutes), the system goes into Sleeping.
- You can configure the system to start processing automatically; otherwise, click Start or press F11 to start processing, and click Stop or press F12 to stop processing.
- Configure Auto Start, BOD time, End of Sequence, and Sleeping mode in Configuration / General / System.

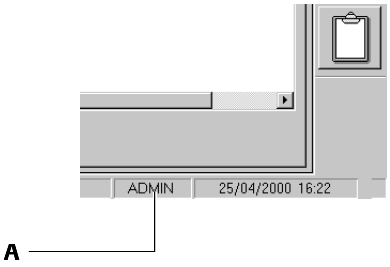
Logging onto the system

To log on, you must use the password and user ID that were created for you by your system supervisor. The software uses the ID of the person who is logged on to record their actions.

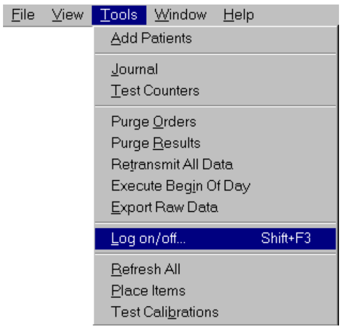
► To log on

1 Use one of the following methods to open the dialog box:

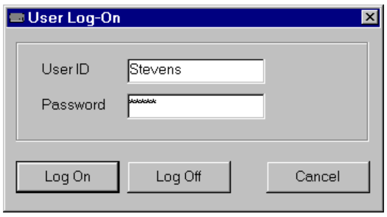
- Press Shift + F3.
- Double-click the user ID (A) in the status bar.



- Choose Tools > Log on/off, in any work area.


File
View
Tools
Window
Help
Add Patients
Journal
Test Counters
Purge Orders
Purge Results
Retransmit All Data
Execute Begin Of Day
Export Raw Data
Log on/off... Shift+F3
Refresh All
Place Items
Test Calibrations

2 Type your user ID and password:


User Log-On
Log On
Log Off
Cancel

User ID Stevens

Password *****

3 Click Log On.

The system activates the buttons on the navigation bar. You now have access to the system, depending on your user access level.

Tip

Your user access level determines the system features that are available to you. Contact your system supervisor if you do not have the privileges you require. The user privileges are defined in Configuration / General / User access and Configuration / General / User level.

What if?

My password is rejected

Check whether you have typed your password and user ID correctly:

- Spaces are not allowed
- The password is case-sensitive, so make sure that you type it exactly as it is defined. For example, the following are different passwords: DOWnie, downie, DOWNIE.

Another user is logged on

Ask the other user to log off, or click Log Off in the User Log-On dialog box. You can then log on.

Logging off and shutting down the system

The following procedures apply to the hardware configuration of Cedex Bio HT analyzer only.

For steps to be performed in connection with messages and troubleshooting

"Putting the system into Standby" on page E-11
"Stopping and restarting the system" on page E-12

Logging off the system

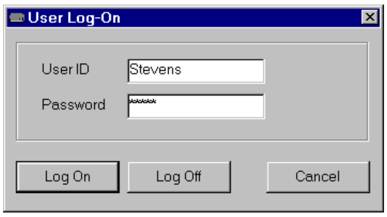
Logging off leaves the system ready for the next user. When you log off, the system removes your user ID as the current user and replaces it with None.

► To log off

1 Use one of the following methods to open the User Log On dialog box:

- Double-click the user ID in the status bar.
- Choose Tools > Log on/off, in any work area.
- Press Shift + F3.

The Log On/Off dialog box is displayed:



User ID: Stevens
Password: *****

2 Click Log Off.

Shutting down the system

If you perform a shutdown, the system waits for a convenient point in the processing, then closes all work areas and dialog boxes, closes down the operating system, and cuts the power.

► To shut down the system

1 Perform any necessary end-of-day tasks.

This step is not necessary if you shut down the system as part of a troubleshooting action.

2 Choose File > Shut Down.

Your are asked to confirm.

The computer is switched off automatically.

3 Switch off the instrument at the main switch.

4 Switch off the printer.

This step is only necessary if your printer has an On/Off switch.

5 Switch off the monitor.

Tips

- Once you initiate a shutdown, you cannot use the system for about 15 minutes.
- After shutdown, certain maintenance procedures will be run automatically from a separate standby power supply.
- The instrument is designed to run continuously, so there is no need to switch it off every day, unless that is a requirement in your laboratory.

Shutting down the ISE module

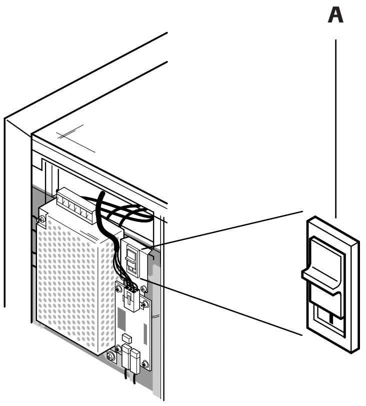
The instrument provides an ISE standby power supply unit. When the instrument is switched off at the main switch, this standby power supply continues feeding the ISE module to perform continuous maintenance. This is necessary to prevent damage to the electrodes and the build up of blockages in the tubing.

"ISE Standby" on page F-10

Caution

Do not switch off the ISE standby power supply.

If for some special reason, you need to switch off this power supply, make sure you use the Roche Diagnostic software and perform this task under the guidance of Roche Service personnel only.



A *On/Off switch for the ISE standby power supply unit (left side of the instrument).*

(Re)Starting and stopping a run

Start

Start

The Start button serves to start or restart a run.

When the system is in the Stopped, AutoService, or Operating status, the text of the Start button changes to Restart.

Tips

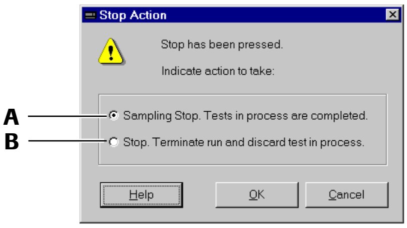
- Clicking Restart causes the system to perform a re-scheduling of all tasks. For example, clicking Restart after inserting a new rack into the system while in Operating status, causes the system to start pipetting on the sample rack that is positioned furthest to the left.
- In terms of system states, clicking Start changes the state from Sleeping to Initializing or from Standby to Operating.

Stop

Stop

The Stop button serves to interrupt sampling or to stop sampling once the current actions are finished.

When clicking Stop, the Stop Action dialog box is displayed, which offers the Sampling Stop and the Stop options:



Stop has been pressed.

Indicate action to take:

● Sampling Stop. Tests in process are completed.

○ Stop. Terminate run and discard test in process.

A *Stop pipetting samples but finish processing tests that are already in progress.*

B *Stop all system operations immediately. The system aborts all current activities. The system may need special attention before it can resume its normal operation.*

Tips

- In terms of system states, clicking Stop changes the state from Operating to Standby or from Standby to Sleeping.
- Tests that were interrupted are marked as blocked and displayed in the corresponding folders in the Status work area and in the Worklist.

Handling test materials

Loading samples

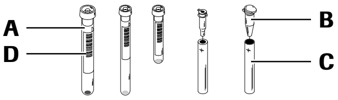
The following table gives information about loading samples, depending on whether the sample tubes have barcodes, and the information given by the barcode.

Barcode	Sample information	Comment
Yes	Yes	Load samples onto any rack defined for that tube type. Barcodes are read automatically.
Yes	No	Load samples onto any rack with the correct default sample type.
No	No	Use the Automatically Assign Rack Position function to automatically assign samples to rack positions. Then use the Sample Handling dialog box to confirm the position or change it. You can also use the Place Items function to manually assign samples to rack positions.

Use only tube and cup types that are defined on your system in Configuration / Lab / Sample Tubes.

► To load samples

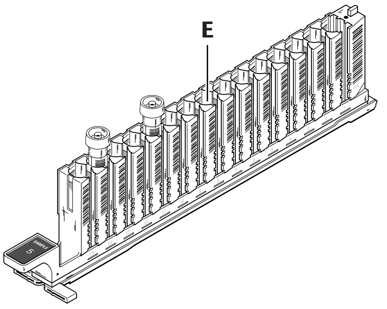
1 Load the samples in primary tubes, secondary tubes (A) or in cups (B) on adapters (C).



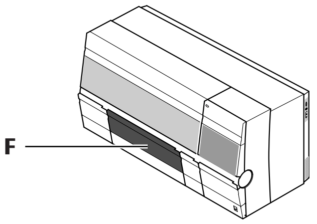
The tubes may have barcodes (D).

2 Place the sample tubes or cups into the rack (E).

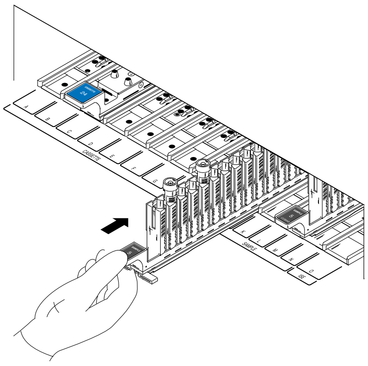
Ensure that barcodes, if used, face to the right when you insert the rack, and that the grid level corresponds with that defined for the tube type (Configuration / Lab / Racks).



3 Open the rack area access panel (F).



4 Insert the rack into one of the five slots (labeled J, K, L, M, or N) in the sample area.



5 Push the rack a short way (about 2 cm) into the slot until you feel the resistance of the stop pin.

6 Look at the rack status panel above the slot you are inserting the rack into. When the LED changes from red to green, push the rack all the way into the slot.

Rack status panel (LEDs):

Red	Rack in use, do not remove.
Red blinking	Rack cannot be identified.
Orange blinking	Rack has not been properly inserted.
Green	OK to use; processing complete.

7 Close the rack access panel.

8 Use the worklist to check your sample placements.

Tips

- You must use only one tube type per rack.
- Racks must be defined for a particular tube type. To check this, use Configuration / Lab / Racks.
- If you use any other types of tubes than those defined on your system, you risk damaging the probes, which have to be replaced before you can continue.
- An orange blinking LED on the rack status display means the system could not identify the barcodes. Remove the rack from the instrument, check the sample and rack barcodes and insert it again.

- The samples on the left most rack (rack in slot with lowest position letter) are measured first, followed by those on the rack next to it on the right.

Loading calibrators, controls, and diluents

You have to load the calibrators, controls, and diluents that the system needs to process the daily workload.

If calibrators and controls have barcodes, you can simply load them on board. The system identifies the locations of the calibrators and controls from the barcodes.

If you do not use barcodes, assign solutions to rack positions in Configuration / Lab / Reserve Positions. You can then print the assigned rack positions, or you can view them in the Samples tab in the Status work area.

Tips

- If you have a set of calibrator levels to load, you must have enough available positions on the rack for all the calibrator levels in the set. You must put multi-set calibrators in continuous positions on the same rack, starting with the highest concentration standard furthest away from you when you insert the rack.
- Consider loading frequently used controls on a rack in slot I, in the cooled cassette area.
- If barcodes for calibrators with several standards are used, label all standard cups with the same barcode
- If you use any other types of tubes than those defined on your system, you risk damaging the probes, which may have to be replaced before you can continue.

Loading cassettes

Cassettes contain up to three reagents and are usually refrigerated, both before use, and on the instrument. Some reagents have to be reconstituted before use.

If a cassette is reloaded on the instrument (for example after storage in the fridge), in certain circumstances the cassette information may have been deleted from the database and the cassette can no longer be used. This is the case if one or more of the following conditions were met while the cassette was off board:

- The lot expiry date had passed
- On-board stability had expired
- At least ten accepted calibration results exist for this cassette
- The cassette had not been used for 180 days

Warning

Do not interchange cassettes among different Cedex Bio HT systems and instruments. Each cassette rack with its cassettes may be used on one individual Cedex Bio HT instrument only. Each cassette has its own individual cassette number, which the instrument uses to identify it. Using a cassette already used on a different Cedex Bio HT instrument may lead to incorrect results.

If more than one Cedex Bio HT instrument is used in the same lab, be sure to dedicate each cassette rack with its cassettes to one single, individual instrument (e.g. by color coding).

What if?

I put the rack back in another slot	If you insert the rack into another slot, the system will identify the rack and the slot.
I cannot print the worklist or loadlist	Check whether the printer is connected, switched on, and whether there is a supply of paper in the printer. Make sure you have the user access level for printing (Configuration / General / User Level). If a new printer was installed for your system, ask your system administrator to check whether the appropriate Windows XP printer driver is installed. (Other drivers will not work on Windows XP.)
I need to load multiple cassettes	You can load additional cassettes at any time.
The new cassette belongs to a different test lot	If you have used up the current lot, load a new cassette. The system will detect the difference in lot numbers and perform a new calibration if necessary.
The system does not recognize the new cassette	Check whether the barcode is damaged, whether it is correctly positioned and whether the cassette is correctly inserted. If the problem persists, check the barcode scanner itself, making sure that the beam is not cut off in any way. Also, check whether you have loaded the cassette definition for the cassette in question. On the Cassettes tab in the Status work area, the cassette is displayed in red, with the status Unknown Fluid.
The new cassette is past its expiration date	The system will detect this; the button turns yellow. Do not use expired cassettes.

Managing resources

Use the Analyzer tab in the Status work area to review the status of on-board resources. The color of each icon shows the status of the corresponding resource.

Checking resources

If you need to take some action to keep the system running efficiently, the background color and the picture on the Status button change: for example, if cuvettes are running low, you see the cuvette icon with a yellow background.

Background color	Take action
Red	Immediately
Yellow	Soon (when convenient)
Green or gray	None

If the analyzer icon is displayed, there are no resource problems.

Resource status

The Status button shows the resources that need to be replaced.

Status button	Resource	User action
	Cleaner	See “Replacing the cleaner” on page B-43.
	Cuvettes	See “Refilling the cuvette reservoir” on page B-44.
	Water	See “Refilling the external water reservoir” on page B-45.
	Cuvette waste	See “Replacing the cuvette waste box” on page B-48.
	Waste drain	See “Emptying the external waste reservoir” on page B-47.
	Temperature	See “Replace ventilation filter” on page D-49. See “Checking and replacing fuses” on page E-40.
	ISE solutions	Check the ISE tab in the Status work area for more information. See “Replace ISE solutions on the ISE rack” on page F-32. See “Replace bottles on ISE module” on page F-34.

Replacing the cleaner

If the cleaner is nearly used up, or if the cleaner temperature is between 36.6°C and 37°C the system warns you by displaying the cleaner icon with a yellow background. The icon is displayed both on the navigation bar and in the Analyzer tab in the Status work area.

The system automatically detects that cleaner has been replaced and resets the icons to their normal states.

Replacement cleaner bottle must have a minimum volume of 250 mL.

If the system completely runs out of cleaner, or if the cleaner temperature exceeds 37.5 °C, the icon turns red and the system stops.

Tools and materials

- 1000 mL bottle of cleaner (Art. 07 5476 5, US 47048 or equivalent)
- Paper tissues
- Protective gloves

Precautions Cleaner contains hydrogen chloride. Use standard laboratory safety procedures when using hydrogen chloride solution.

Danger

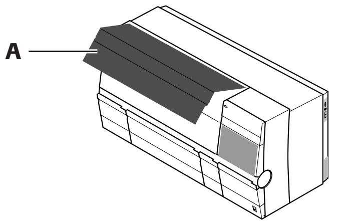
- *Wear protective gloves.*
- *Replace the cleaner bottle only while the system is in Standby or Sleeping status, or while it is switched off.*
- *Do not open the front cover while the system is running.*

Caution

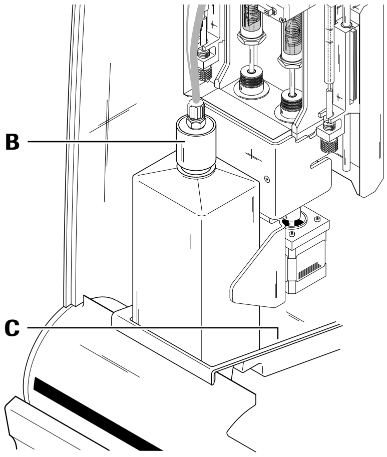
Main front cover
Danger of injury due to closing main front cover. If the main front cover is not opened completely it might close unintentionally by itself.
Whenever you open the main front cover, be sure to open it as far as it will go.

► To replace the cleaner bottle

1 Open the main cover (A), be sure to lift it as far as it will go.



2 Remove the cap (B) from the existing cleaner bottle and place the level detection sensor and tubing carefully to one side.



3 Discard the used cleaner bottle.

4 Remove the cap from the new cleaner bottle and place the bottle in the slot provided (C).

5 Reinsert the sensor and tubing. The cap (through which the tubing passes) should fit loosely on the top of the bottle.

6 Close the main cover.

Refilling the cuvette reservoir

When the cuvette icon turns yellow (in Status / Analyzer or on the Status button) you must refill the cuvette reservoir before the system runs out of cuvettes. The number of cuvettes that are still available for use is displayed in the Analyzer tab in the Status work area. You can perform this task at any time while the system is running. When the icon is red, the system stops.

The cuvette reservoir can hold a maximum of 1400 cuvettes. Each pack contains approximately 1000 cuvettes.

Tools and materials

- New pack of cuvettes
- Pair of scissors

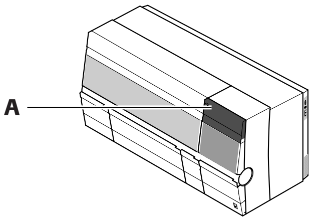
Precautions

Warning

- *Make sure that you do not touch the surface of any cuvettes; result accuracy may be affected.*
- *Make sure that the cuvette drawer slide is always clean and that you replace it properly when you have completed this task.*

► To refill the cuvette reservoir

1 Open the cuvette reservoir access panel (A).

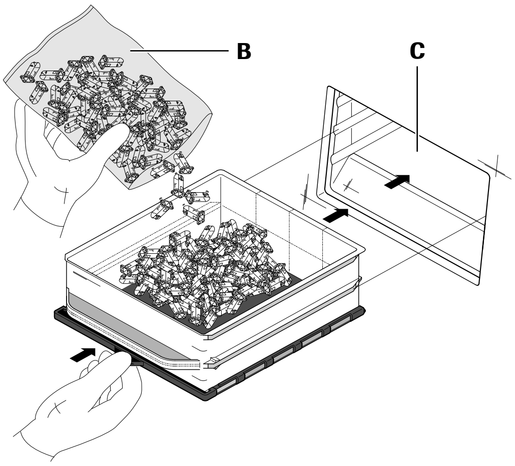


2 Remove the cuvette reservoir together with the covering slide.

Do not remove the slide from the reservoir.

3 Turn the cuvette reservoir upside down.

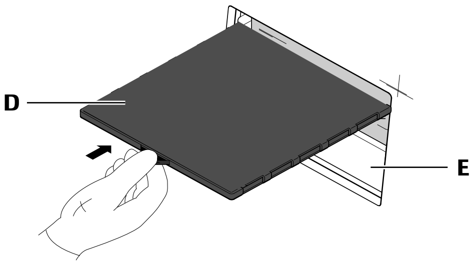
4 Cut open the cuvette pack (B) and, taking care not to touch the cuvettes, pour the cuvettes into the reservoir.



5 Reinsert the reservoir and the slide back into position (C).

6 Remove the slide, taking care not to spill any cuvettes.

7 Replace the slide (D) at the top or the reservoir (E).



The system automatically detects that the cuvette reservoir has been refilled.

Refilling the external water reservoir

You do not need to perform this task if your system is connected directly to a laboratory water supply. However, you will get a resource alert, if the laboratory water supply pressure drops below the required value.

When the water supply icon turns yellow (in Status / Analyzer or on the Status button), you must refill the external water reservoir. When the icon is red, the system stops.

The system cannot operate without a water supply, but you can disconnect it temporarily while the system runs from the internal water reservoir. When the internal water reservoir becomes empty, the system stops.

Location The external water reservoir is usually located underneath the instrument. The reservoir is a 10 L white plastic reservoir, labeled "Reservoir".

Tools and materials

- 10 L of reagent grade, type 1 water
- 1000 mL beaker

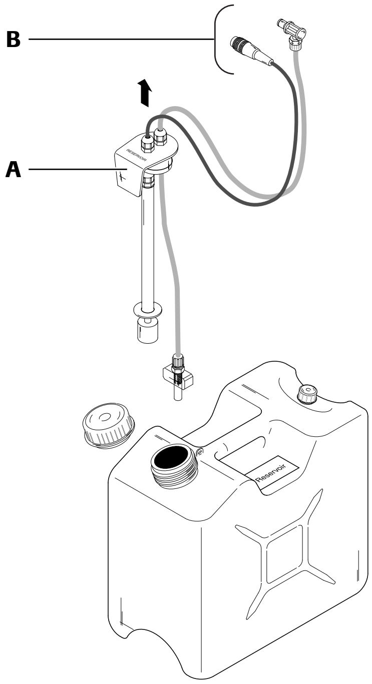
Precautions

Warning

Always use water that meets the required purity standards. Failure to do this can affect result accuracy and cause general maintenance problems.

► To refill the external water reservoir

1. Remove the tubing adapter (A) from the reservoir and put it temporarily into a clean empty 1000 mL beaker.



2. Refill the reservoir with reagent grade, type 1 water.
3. Insert the tubing adapter into the reservoir.

Tips

- The system can run off the internal water reservoir for a short time. If you perform this task promptly, you can avoid having the system shut down due to lack of water.

- You do not have to disconnect the water reservoir (B) connectors from the rear of the instrument.

Emptying the external waste reservoir

You do not need to perform this task if your system is connected directly to a laboratory waste system. However, you will get a resource alert, if the laboratory waste system becomes blocked.

If the waste drain icon turns yellow or red (in Status / Analyzer or on the Status button), you must empty the external waste reservoir.

Location The external waste reservoir is usually located underneath the instrument. The reservoir is a 10 L yellow plastic container, labeled “Waste”.

Tools and materials

- Protective gloves
- Disinfectant
- 1000 mL beaker

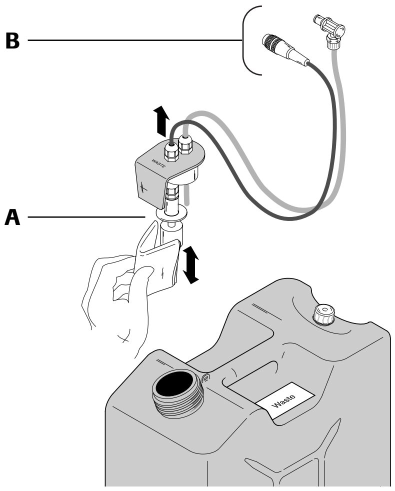
Precautions Fluid waste is potentially infectious and must be handled using proper safety precautions.

Warning

- *Always wear protective gloves while working with fluid waste.*
- *Clean any spills immediately according to the procedures established for your laboratory.*

► To empty the external waste reservoir

1. Ensure that the system is in Standby or stopped (switched off).
2. Remove the tubing adapter (A) from the reservoir and place it temporarily in a clean 1000 mL beaker.



3. Dispose of the fluid waste according to the procedures established in your laboratory.
4. Rinse the waste reservoir with disinfectant and then water.
5. Replace the tubing adapter.

6 Restart the system, if necessary.

Tip

Step 2: You do not have to disconnect the electrical and waste connectors (B) from the rear of the instrument.

Replacing the cuvette waste box

The cuvette waste box stores fluid waste from the ISE module, and up to 1000 used cuvettes.

When the yellow Cuvette Waste Box icon appears (in Status / Analyzer or on the Status button), you must replace the cuvette waste box as soon as possible, and confirm that you have done so. When the icon is red, the system stops.

The cuvette waste box can store up to 1000 cuvettes, and the Cuvette Waste Box icon turns yellow as soon as about 800 used cuvettes are in the box.

Tips

- Replace the cuvette waste box while the system is in Standby, and avoid replacing it while the box is being shaken.
- The filling status of the waste container is determined only by the cuvette counter. The waste volume is not monitored by the system. A regular check of the waste container level is recommended.

Tools and materials

- Protective gloves
- Cuvette waste box

Precautions

Cuvette waste is potentially infectious and must be handled using proper safety precautions.

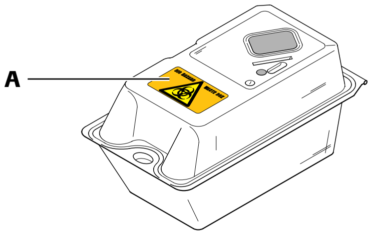
Warning

- *Always wear protective gloves while working with cuvette waste.*
- *Clean any spills immediately according to the procedures established for your laboratory.*
- *Never tilt the waste box. If you do so, there is a risk of spilling of contaminated waste if the waste box is not properly closed.*
- *Store the removed waste box in an autoclaves plastic bag or dispose the waste box immediately.*
- *Dispose of the old cuvette waste box and its contents according to your local regulations for the disposal of hazardous waste.*

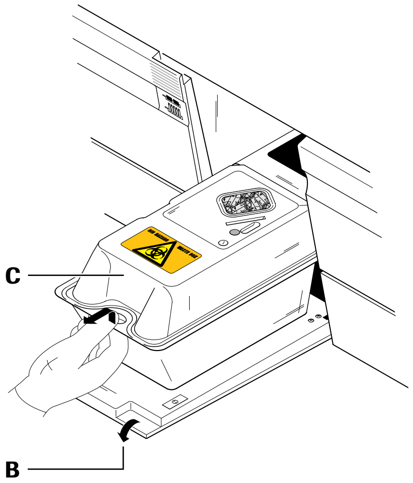
► To replace the cuvette waste box

1 Wait until the system is in Standby.

2 Construct the new cuvette waste box according to the instructions inside the cuvette waste access panel (B). The cuvette waste box is supplied with a yellow bio-hazard sticker already in place (A).

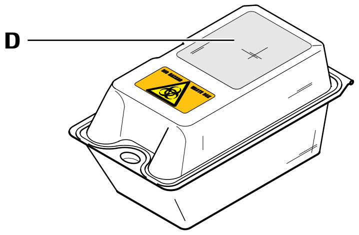


3 Open the cuvette waste access panel (B).



4 Remove the full cuvette waste box (C), taking care not to spill any of the contents.

5 Put a rectangular sticker (D) over the holes in the top of the waste box.



6 Insert the new waste box, taking care to ensure that the lip around the middle of the box fits into the guide rails.

7 Close the cuvette waste access panel.

The system asks you whether the cuvette waste box is empty.

8 Click Yes, if the new box is empty.

9 Dispose of the old waste box and its contents according to your local regulations for the disposal of hazardous waste.

Checking due service actions

Service actions are tasks that keep the instrument running properly. In some service actions all the steps are performed automatically; others have some steps that you must perform manually.

If the button color is...	Do this...
Grey	No action is required.
Yellow	Perform the due service action as soon as possible.
Red	Take immediate action! As a first step, back up the database immediately. Then perform the due service action(s).

► To perform due service actions

Check the Service button on the navigation bar. If its background is yellow:

1. Click Service on the navigation bar.
2. Select one or more service actions from the list.
3. Click Perform.
4. Perform the service actions according to the on-screen instructions.

   Click Help for full details.

Tip

- Should you have chosen to not perform the Backup database service action automatically at BOD (Service > View Counters / Service Intervals), then if the Backup database service action is due, perform it at the end of the day. This service action may take about 5 minutes.

Caution

Database backup must be performed in regular intervals otherwise the accumulated data will fill all available space on the hard disk and the system will be blocked.

Chapter 13, “Service action software”
Chapter 14, “Service actions”

Checking the Memo Pad

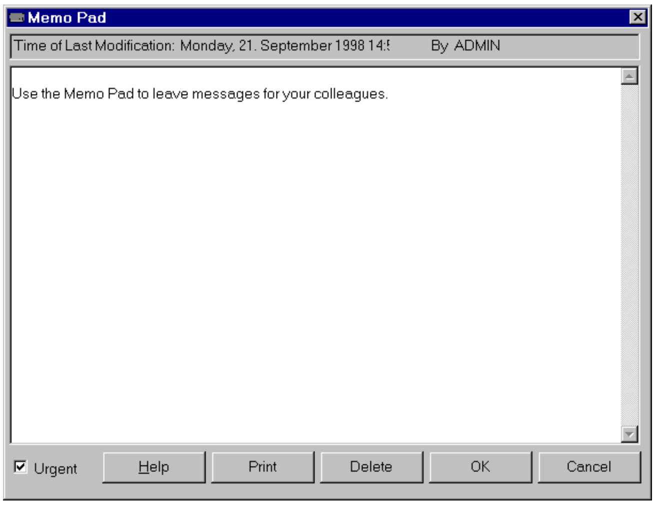
The Memo Pad may contain messages from other users. You recognize the urgency of a message by the color of the icon on the Memo Pad navigation button:

- For urgent messages, the icon text is displayed in white font on red background.
- For normal messages, the icon text is displayed in white font on blue background.
- If there are no messages the icon is displayed all white.

► To read the Memo Pad

Click Memo Pad on the navigation bar.

The Memo Pad dialog box is displayed.



Time of Last Modification: Monday, 21. September 1998 14:5 By ADMIN

Use the Memo Pad to leave messages for your colleagues.

☑ Urgent

► To leave a message for another user

1 Click Memo Pad on the navigation bar.

The Memo Pad dialog box is displayed.

2 Type your message.

3 Select the Urgent check box if the message is urgent.

4 Click OK.

Tip

The Delete button deletes all text on the dialog box. To delete selected text, use the Delete key on your keyboard.

Printing reports

The table below shows the reports that are available in each work area.

Report	Available in work area	Choose
Begin of Day (BOD)	Status, Orders, Results, Service, and Configuration	File > Print Report > Begin of Day
Final Report	Status, Orders, Results, and Configuration	File > Print Report > Final Report
Journal	Status, Orders, Results, and Configuration	Tools > Journal, then click Print
Loadlist	Status, Orders, Results, and Configuration	File > Print Report > Loadlist
Missing & Blocked	Status, Orders, Results, and Configuration	File > Print Report > Missing & Blocked
Quality Control	Results	File > Print QC Report
Results	Status, Orders, Results, and Configuration	File > Print Report > Results
Service Counters	Service	File > Print Report > Service Counters
Service Intervals	Service	File > Print Report > Service Intervals
Service Notes	Service	File > Print Report > Service Notes
System Counters	Service	File > Print Report > System Counters
Test Counters	Status, Orders, Results, and Configuration	Tools > Test Counters, then click Print
Worklist	Status, Orders, Results, and Configuration	File > Print Report > Worklist

The reports are described in the following sections.

Tip

Your printing rights are defined in Configuration / General / User Level.

Printing the Begin of Day report

The Begin of Day report serves as a check list during daily start-up (see “Daily start-up” on page B-8). The report provides information on events that took place while the Begin of Day actions were performed, and it also lists actions that were not performed successfully and therefore may require user intervention.

The Begin of Day report is structured in the following way (only those headings are listed in the report for which there are entries):

- Following Begin of Day actions were not completed:

  Service actions that are programed to be performed automatically at BOD, but were not completed successfully.

- Following service actions need to be performed:

  Service actions that are due. An Elapsed value of 100% means that the action is due now, a value smaller than 100% means it will be due soon, a value greater than 100% means that the action has been due for some time.

  This list includes all service actions that are due.
- Test with pending calibration or control requests:
- Tests with postponed calibration:
- Required Calibrators, Controls, Cleaners, Diluents, and ISE Fluids:

  The required calibrators, controls, cleaners, diluents, and ISE Fluids necessary to run the pending calibrator and control requests together with their status (for example Blocked) are displayed.
- Following cassettes need to be handled:

  This information is identical with that displayed in the Cassettes group on the Missing & Blocked tab of the Status work area.

► To print a Begin of Day report

1 Choose File > Print Report > Begin of Day from the menu bar.

2 The Print dialog box is displayed.

3 Click OK.

Tip

Place all calibrators on the system before you print the BOD report. (The system updates the calibrator status of onboard calibrators only.)

Printing the Final Report

The Final Report lists order details, and accepted test results for a single sample.

The header information of the Final Report is defined in Configuration / Processing / Report Layout. To specify the reporting order for tests, use Configuration / Processing / Report Layout, and click Print Sequence.

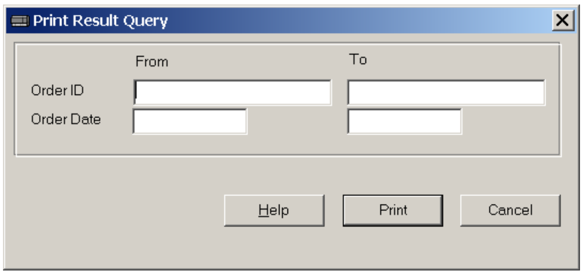
System-specific flags are not included in the report. They would be of no use to the doctor.

► To print a Final Report

1 Click Status, Orders, Results, or Configuration on the navigation bar.

2 Choose File > Print Report > Final Report from the menu bar.

The Print Result Query dialog box is displayed



3 Type the values to define your selection.

If you do not provide any selection criteria, all available results will be included in the report.

4 Click Print to generate the report and print it.

Test-specific ranges and limits shown on the report

- Reference ranges are given in numbers.
- For quantitative tests, results outside the defined reference range are presented the following way:
    - H (high) stands for “> RR” and “> Critical Range”
    - L (low) stands for “< RR” and “< Critical Range”
- For qualitative tests that depend on the direction of the reaction, the following abbreviation is used:
    - POS: The value is above the cutoff limit

      (The cutoff limit is defined in Configuration / Tests / Evaluation.)

Calculated results (ratio)

You can print a calculated result together with the tests these results are based on. In Configuration / Processing / Report Layout / Print Seq., you can define where in the report the calculated results should appear.

Printing the Final Report automatically

You can choose to have the Final Report printed automatically, without any user intervention.

► To have a report printed automatically

1 Click Configuration on the navigation bar.

2 Double-click Database in the System group.

3 Click the Automatic Actions tab.

4 Select Final Report from the Automatic Printouts list.

5 Click OK.

6 The Final Report will be printed as soon as:

- All tests of the order are complete.
- All results associated with the order are accepted.

Printing the Loadlist

The loadlist contains all orders known to the system. They are listed by their rack positions in ascending order, starting with the lowest rack position of the rack with the lowest rack number. The list shows all rack positions to which samples were assigned, either automatically by barcode reading or manually (see “Assigning samples to racks” on page B-96).

If you work with barcodes and without a host system, or if you work without barcodes, use this list to load the samples on the correct position on the sample racks.

► To print the load list

1 Click either Status, Orders, Results, or Configuration on the navigation bar.

2 Choose File > Print Report > Loadlist from the menu bar.

The Print dialog box is displayed.

3 Click OK.

Printing the Missing & Blocked report

The Missing & Blocked report allows you to produce a printout of the information stored on the Missing & Blocked tab in the Status work area.

The entries are listed under the headings

- Cassettes
- Calibrators, Controls, Cleaners, ISE
- Samples

► To print a Missing & Blocked report

1 Click either Status, Orders, Results, or Configuration on the navigation bar.

2 Choose File > Print Report > Missing & Blocked from the menu bar.

The Print dialog box is displayed.

3 Click OK.

"Missing & Blocked tab" on page B-68

Printing results

There are two ways of printing results:

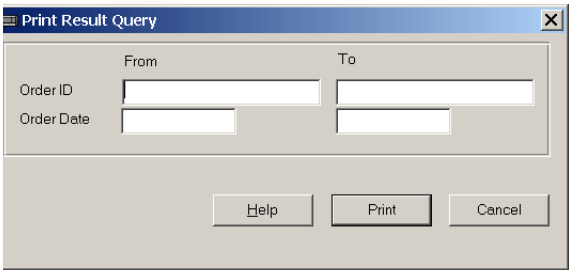
1. You can print a cumulative results report.
    - The Results report lists every result (accepted and unaccepted) on the system.
    - You can specify ranges for order ID and for the order date.
    - The results are listed by order ID in ascending order.
    - For each order creation date, a new page is started.
2. You can print the results of a single order.

► To print the Results report

1 Click Results on the navigation bar.

2 Choose File > Print Report > Results from the menu bar.

The Print Result Query dialog box is displayed.



3 Type the values to define your selection.

If you do not provide any selection criteria, all available results will be included in the report.

4 Click Print to generate the report and print it.

► **To print the Results of a single order**

1 Click Results on the navigation bar.

2 Right-click the order ID and choose Print Preview from the context menu.

3 Click Print in the Report Preview dialog box.

Printing the Worklist

The worklist contains all orders known to the system. They are listed by their order IDs in ascending order. It shows the orders that require completion, the tests ordered for each sample, and the status of each test.

If you work with barcodes and without a host system, or if you work without barcodes, use this list to get an overview on the orders and tests that need processing.

► **To print the worklist**

1 Click either Status, Orders, Results, or Configuration on the navigation bar.

2 Choose File > Print Report > Worklist from the menu bar.

3 The Print dialog box is displayed.

4 Click OK.

Printing the journal

The journal lists all results in chronological order of their pipetting time. Use this information to review the pipetting sequences of tests run on the system, or to troubleshoot the causes of carry-over errors. For example, you can run a sequence of test trials to isolate which tests are responsible and then specify extra wash cycles to solve the problem.

Caution

The flag listed in the Journal for a specific test is not necessarily the final flag for that test. The flag, if any, in the Journal is a temporary flag that was active when the pipetting took place. This flag is often overwritten or removed from the final result. To review flags for a result, use the Sample, Calibration, or Quality Control tabs in the Results work area.

► **To print the journal**

1 Click either Status, Orders, Results, Configuration, or Service on the navigation bar.

2 Choose Tools > Journal from the menu bar.

The Journal dialog box is displayed.

3 Select the items you wish to print, and click Print.

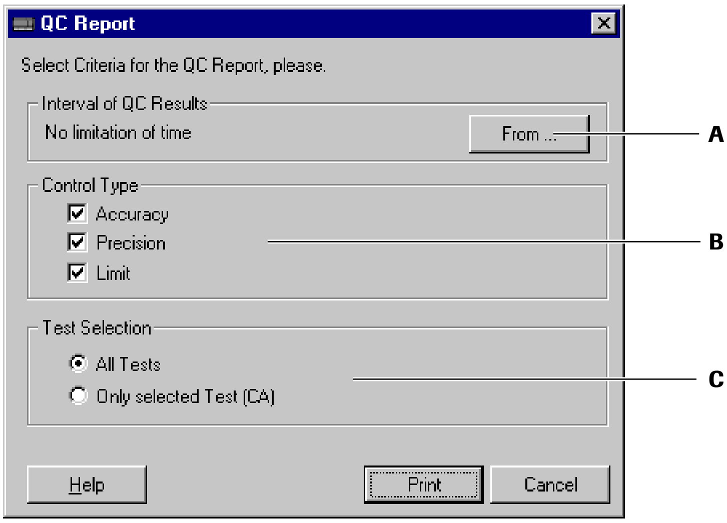
Printing Quality Control reports

Use the Quality Control reports to review the quality control history of individual tests. You can select what results you want to include in the reports.

Content and layout of the report depend on the view type you selected in the folders list of the Quality Control tab.

Selected features of a Quality Control report

- A Quality Control report consists of several separate reports, one for each test and one for each control type.
- Each single report contains for one test the results of up to three controls of the same control type. Should there be more than three controls for the same control type, the report is split. The first report contains the results of the first three controls, the second report those of the next three, or the remaining controls.
- The page numbering in the printed Quality Control report refers to the single reports.
- As part of the printing process, you can specify the data you want to include in the report. Choose File > Print QC Report from the menu bar, and the QC Report dialog box is displayed. The following figure shows the QC Report dialog box with the By Test view selected:



Select Criteria for the QC Report, please.

Interval of QC Results
No limitation of time

Control Type
☑ Accuracy
☑ Precision
☑ Limit

Test Selection
● All Tests
○ Only selected Test (CA)

A *Set the period for which the QC report should be generated.*

B *Select the control types for which a report should be generated. These settings will remain active when this dialog is opened the next time. If you do not select any type, no report will be generated and printed. If multiple control types are selected, QC is printed more than once.*

C *Choose whether a report should be generated for the controls of the selected test only or of all tests. If you select Only Selected Test, the results of all controls of the test will be printed, irrespective of what level you selected on the By Test list of the Quality Control tab. The Only Selected Test option is only available while a test is selected in the folders list of the Quality Control tab.*

► To print a Quality Control report from the By Test view

1. Click Results on the navigation bar.
2. Click the Quality Control tab.
3. Click the column header to display the By Test View.
4. Select a test in the By Test column, if you want to print a report for a certain test.
5. Choose File > Print QC Report from the menu bar.

   The QC Report dialog box is displayed.
6. Use From to set the period for which the QC report should be generated.
7. Select the control types for which a report should be generated.
8. Choose whether a report should be generated for the controls of the selected test

only or of all tests.

9 Click Print.

The Progress of QC Report dialog box is displayed.

You can click Cancel to stop the report generation.

Tips

- The period you set for which the QC report should be generated, is valid for generating the report only. It does not affect the filter settings set in the Results work area.
- Step 5: To simply print the statistics of the selected test, click Statistics, and then click Print in the Results QC Statistics dialog box.

► **To print a Quality Control report from the Control view**

- Click the column header to display the By Control view, and proceed as when printing from the By Test view.

Printing service counters

The service notes report contains the information of the Service Counters dialog box (Service > View > Counters).

► **To print the service counters**

1 Click Service on the navigation bar.

2 Choose File > Print Report > Service Counters from the menu bar.

The Print dialog box is displayed.

3 Click OK.

“Service Counters dialog box” on page D-15

Printing service intervals

The service intervals report contains the information of the Service Intervals tab on the Service Counters dialog box (Service > View > Counters).

► **To print the service intervals**

1 Click Service on the navigation bar.

2 Choose File > Print Report > Service Counters from the menu bar.

The Print dialog box is displayed.

3 Click OK.

“Service Intervals tab” on page D-16

Printing service notes

The service notes report contains the information of the Service Notes dialog box (Service > View > Notes).

Added notes to Service notes are printed immediately after the note they were added to. The original note is marked with the 📎 symbol.

► To print the service notes

1. Click Service on the navigation bar.
2. Choose File > Print Report > Service Notes from the menu bar.

   The Print dialog box is displayed.
3. Click OK.

"Service notes" on page D-13

Printing system counters

The system counters report contains the information of the System Counters tab on the Service Counters dialog box (Service > View > Counters).

► To print the system counters

1. Click Service on the navigation bar.
2. Choose File > Print Report > System Counters from the menu bar.

   The Print dialog box is displayed.
3. Click OK.

"System Counters tab" on page D-17

Printing test counters

The service notes report contains the information of the Test Counters dialog box (Tools > Test Counters).

► To print the test counters

1. Click either Status, Orders, Results, or Configuration on the navigation bar.
2. Choose Tools > Test Counters from the menu bar.

   The Test Counters dialog box is displayed.
3. Use From to set the period for which the test counters should be printed.
4. Click Print.

   The Print dialog box is displayed.
5. Click OK.

"Test Counters dialog box" on page D-18

Purging and deleting information and items

Purging	Eliminating unneeded information systematically.
Deleting	Erasing orders and results without preconditions.

Caution

Do not delete data from the D disk drive or from the Roche directory on the C drive.

Deleting raw data

Raw data are the numerical values of the physical measurements made by one of the measuring modules. Since each result comprises many measurements, the amount of raw data can become very large, very quickly. To prevent this from happening, you can choose either of two options:

- Delete Raw Data after accepting results.
- Delete Raw Data after n days.

► To delete raw data after accepting results

1. Click Configuration on the navigation bar.
2. Double-click Database in the System group.
3. Click the Automatic Actions tab.
4. Select the Delete Raw Data after accepting results check box.
5. Click OK.

► To automatically delete raw data after a certain period of time

1. Click Configuration on the navigation bar.
2. Double-click Database in the System group.
3. Click the Automatic Actions tab.
4. Select the Delete Raw Data after check box.
5. In the Delete Raw Data after box, type the number of days you want raw data to remain on the system.
6. Click OK.

Tips

- Type 0 (zero) to delete at the next Begin of Day all of today’s raw data, that is all raw data generated between the time of the last and the next Begin of Day time.
- Type 1 to delete at Begin of Day all raw data that were generated more than 24 hours before Begin of Day time.

Purging and deleting orders

You can purge orders manually at any time, or delete them automatically at BOD. The main reason for purging orders is to free the order IDs for re-use.

Preconditions You can only purge an order when:

- There are no pending tests belonging to this order.
- The associated results have been accepted.
- The associated results have been transmitted to the host, if necessary.
- The associated samples have been removed from the system.

"To purge orders manually" on page B-109
"To delete orders automatically at BOD" on page B-109
"To delete a single order" on page B-109

Purging results

The *Cedex Bio HT* analyzer is not designed to store safely large quantities of results on the system. As part of data management, you should periodically purge results manually. At least every 2 months is recommended.

The system should be in the Standby or Sleeping state when purging results.

When purging results, the following information is deleted:

- Results
- Calculated results that were derived from purgeable results
- Test orders
- Order IDs

If you archive the results in the results work area you need to purge the results regularly.

Tips

- Before you purge results, you should archive your current calibration, control, and sample results (File > Archive Results).
- To delete a sample, use Results / Sample.
  - Right-click the order ID, and choose Delete.
  - In the Confirm Delete dialog box, click Yes.

For details and procedures on purging results, see

"Purging results" on page B-130
"Preconditions for purging results" on page B-130
"To purge results" on page B-130
"To delete a single result" on page B-131

Database Reorganization

The Database Reorganization function is closely related to the Purge Results function, and should be performed when you just purged large numbers of results, for example the results of the last three months. It reconditions the database and improves the system performance.

Prior to Database Reorganization, you should

1. Backup the database.
2. Purge the results.

Caution

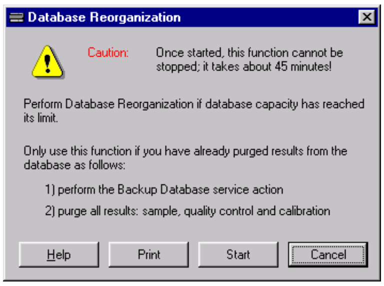
- *Database Reorganization should only be performed under guidance of Roche Service personnel.*
- *Database Reorganization may take up to one hour. Do not interrupt this process!*

► To reorganize the database

1 Click Service on the navigation bar.

2 Choose Tools > Database Reorganization.

The Database Reorganization dialog box is displayed:



Caution: Once started, this function cannot be stopped; it takes about 45 minutes!

Perform Database Reorganization if database capacity has reached its limit.

Only use this function if you have already purged results from the database as follows:

1) perform the Backup Database service action

2) purge all results: sample, quality control and calibration

3 Click Start.

Archiving system information

Some useful hints

To select what data you want to archive, click Configuration on the navigation bar and choose File > Archive Definitions.

Archiving the System Parameters

What is stored?

- General definitions
- Database definitions
- Processing definitions
- Result Handling definitions

What is not stored?

- ISE definitions (General / ISE)
- Lab definitions

Archiving the Complete Test Definitions

What is stored?

- Test definitions, including user-defined test definitions
- Calibrator definitions
- Control definitions
- Diluent definitions
- Cassette definitions
- Cleaner definitions (only if the selected test is entered in the extra wash cycle table)

What is not stored?

- Profiles definitions
- Calculated results (Ratios) definitions
- The following calibrator definitions: lot number, expiry date, and values
- The following control definitions: lot number, expiry date, and values

Status

Review the status of your instrument

This chapter describes the Status work area and how to use it. It shows you how to review the status of samples, cassettes, tests, system resources, and the ISE module.

In this chapter

Chapter **7**

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Status work area overview B-69
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Cassettes tab B-74
Test Status tab B-76
Analyzer tab B-78
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ISE tab B-80
Displaying item details B-81
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About Status

The system continually monitors its status and displays this information in the Status work area. Much of the information is presented graphically, using the following color coding:

Color	Meaning
Green	OK.
Yellow	Caution, you need to do something soon.
Red	Critical, the system has stopped, and you must take corrective action immediately.

The exact meaning of each color depends on the tab.

System-wide alerts

If the system cannot function due to a resource shortage, an icon is displayed on the Status button on the navigation bar. The icon identifies the resource shortage; for example, when the cuvette supply is low, a cuvette icon is displayed. The background color of the icon shows whether the alert is a warning (yellow background) or a critical situation (red background). The Analyzer tab in the Status work area shows the status of all the resources and system temperatures.

Additional information relating to the ISE module is displayed in the ISE tab.

👁 *"Checking resources" on page B-42*

Missing and blocked

The system can perform a test only if all the items required for that test are loaded and all the items are current. The system automatically identifies any missing and blocked items:

Item status	Meaning
Not on Board	The item is not on board.
Blocked	The test (calibrator, control or sample) cannot run because a prerequisite has not been satisfied. For example, the system cannot run a test if the test cassette is not on board. The test is labeled Blocked until you load the required cassette.

Missing and blocked items are listed on the Missing & Blocked tab in the Status work area. By reviewing this information regularly, you can quickly identify the steps you need to take to maintain the throughput of tests on your system.

Status work area overview

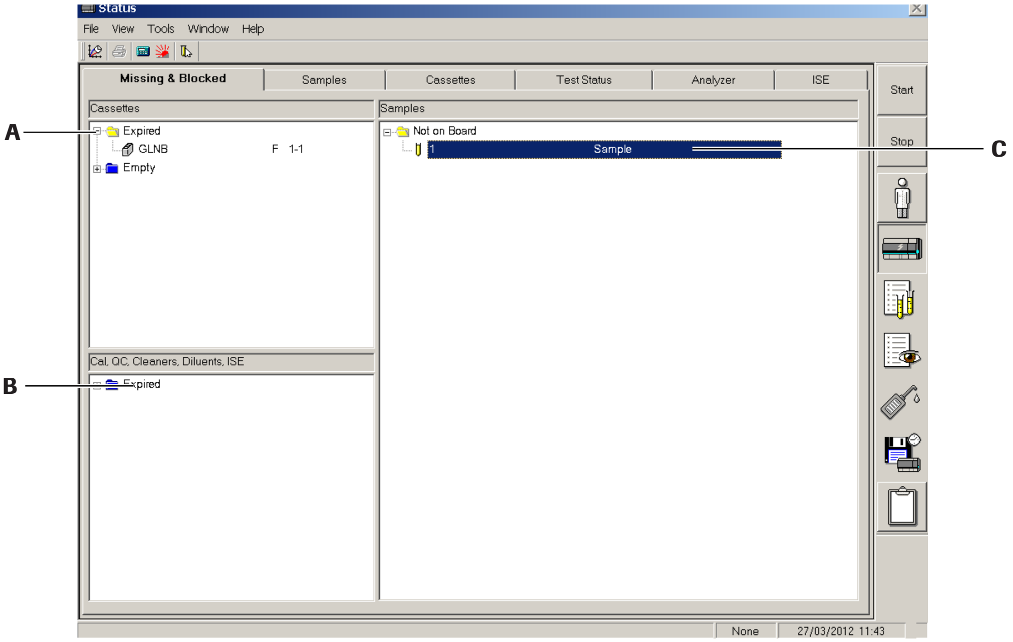
To access the Status work area, click the Status button on the navigation bar, choose Window > Status, or click F7.

The Status work area has six tabs, each of which shows the state of a particular part of the system. The tabs in the Status work area are as follows:

Tab	Function
Missing & Blocked	This tab gives information about: • Cassettes • Calibration, QC, Cleaners, Diluents, ISE • Samples When there is a problem with one of the solutions, for example, if a cassette is empty, or if an on-board sample has no associated order, the relevant information is displayed in this tab.
Samples	This tab gives a graphical representation of the sample racks on the system. The tube positions are color-coded so that you can easily check the status of the samples.
Cassettes	This tab gives a graphical representation of the cassette racks on the system. The cassette positions are color-coded so that you can easily check the status of the cassettes.
Test Status	This tab allows you to display cassette, calibration, quality control, and diluent information for a selected test.
Analyzer	This tab gives an overview of the state of the system. Bar graph indicators tell you about the state of sample processing, and color- coded icons tell you about system resources such as cuvettes and water supply, or the instrument temperature.
ISE	This tab gives an overview of the state of the ISE module. Graphical representations of the electrodes, solutions on the ISE module and solutions on the ISE rack are color-coded so that you can quickly locate any blockages.

Missing & Blocked tab

Use the Missing & Blocked tab to see which samples, calibrations, or controls cannot be processed and why. For example, a sample may be listed as blocked because the cassette required to run a test on that sample is not on board.


Status
File View Tools Window Help
Missing & Blocked
Samples
Cassettes
Test Status
Analyzer
ISE
Start
Stop
Cassettes
Expired
GLNB F 1-1
Empty
Cal, QC, Cleaners, Diluents, ISE
Expired
Samples
Not on Board
1 Sample
None
27/03/2012 11:43
A
B
C

A *Click to expand (if ⊞) or contract (if ⊟) the folder.*

B *Folder name tells you why the item is blocked.*

C *Double-click any line to display detail for that item.*

Tips

- The Missing & Blocked tab does not show items that are correctly loaded and ready to run, or items for which tests have already been run.
- To display the details for an item, do one of the following:
  - Double-click the item.
  - Right-click the item, then choose Item Detail.
  - Select an item and press Space.
- Press F1 to display Help for this tab.
- STAT orders are shown in bold.

Folders on the Missing & Blocked tab

The following table shows the meaning and action required for each folder on the Missing & Blocked tab.

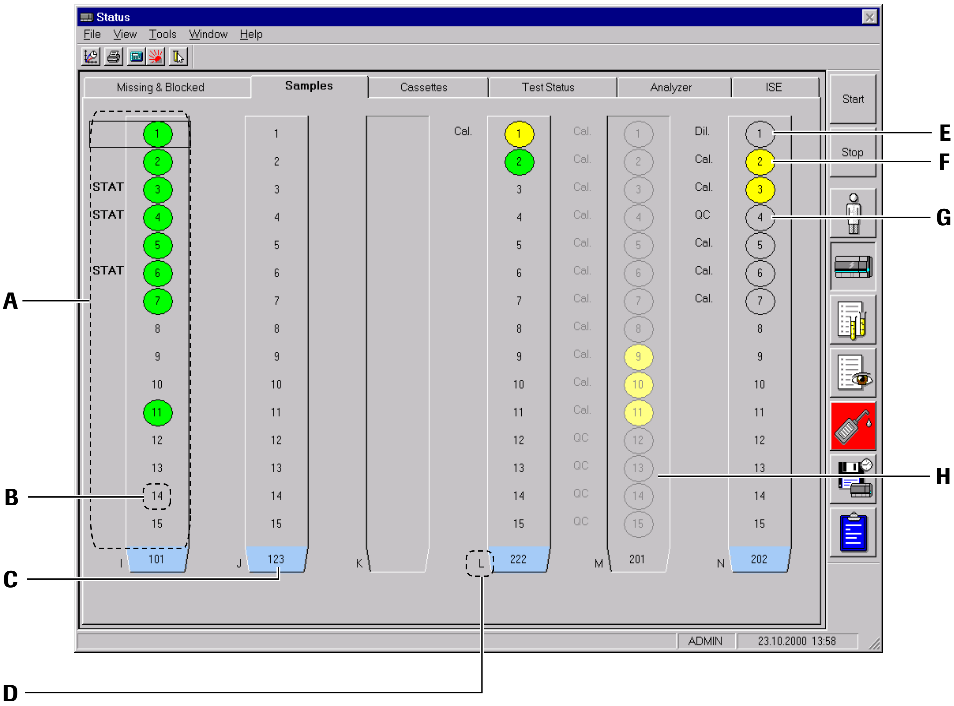
Folder	Meaning	User action
Blocked	The test is blocked because an item is missing or not correctly defined. A test may be blocked because, for example, there is no relevant calibration.	Find the missing items (in other folders) and correct the problem. Details about the calibration for a test can be found in the Test Status tab.
Clot detected	A clot was detected in a probe or in the tubing.	Replace the affected items.
Empty	The item is on board, but it is empty.	Replace affected items.
Expired	The items listed have passed their expiration date. (For cassettes and diluents.)	Replace expired items.
Missing Information	The item is on board, but it is not correctly defined in the system. (For cassettes, diluents and cleaners.)	Use the Configuration work area to load the definition.
Not enough for worklist	The item is loaded, but there is not enough of it to run the tests in the current worklist. (For cassettes only.)	Replace or add more of the missing item. (For example, add additional cassettes.)
Not On Board	The item is not on board.	Load the missing item. For cleaner cassettes and diluent tubes, the Not on Board status is generated only if there is actually an order for the test that needs these cleaners or diluents.
Without Orders	The sample is loaded into the instrument, but there is no order associated with the sample. (For samples only.)	Create an order for the sample or remove the sample.

Tips

- If a category has no entries, the corresponding folders is not listed.
- A sample on the system without an order is listed as Without Order on the Missing & Blocked tab.
- As long as the system is in Standby, the status of blocked cassettes remains Blocked, even if new cassettes were inserted. As soon as the system goes into Operating state, the status of the cassette is updated.

Samples tab

Use the Samples tab to review the status and positions of samples, calibrators, controls, and diluents loaded in slots I through N. You can display details for individual tube positions or for a whole rack.


Status
File View Tools Window Help
Missing & Blocked
Samples
Cassettes
Test Status
Analyzer
ISE
Start
Stop
STAT
STAT
STAT
Cal.
Dil.
QC
I 101
J 123
K
L 222
M 201
N 202
ADMIN
23.10.2000 13:58
A
B
C
D
E
F
G
H

A *Samples*
Double-click any position to display details for that sample.

B *Rack position*

C *Rack number*
Double-click for more details

D *Slot ID*

E *Diluent*

F *Calibrator*

G *Quality control*

H *This rack has been removed.*

Tips

- The color of the sample rack position tells you the status of the sample, calibrator, or control.

  "Color coding on sample rack positions" on page B-71

- To display the details for a rack position, do one of the following:
  - Double-click the rack position.
  - Right-click the rack position, then choose Item Detail.
  - Select a rack position and press Space (or press Enter to display details for the rack).
- Use the same techniques to display details for the whole rack, but click the rack number.
- Racks that have been removed from the system are shown as "greyed-out" (H).

  "Loading samples" on page B-38
  "Loading calibrators, controls, and diluents" on page B-40

- Press F1 to display Help for this tab.

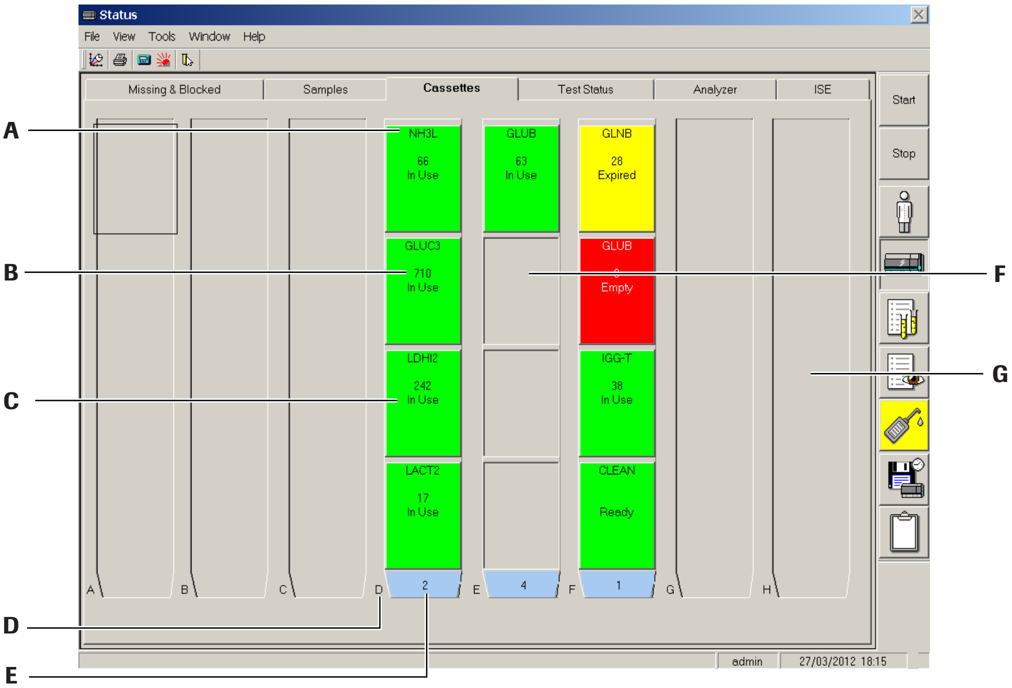
Color coding on sample rack positions

The sample rack positions are color-coded. The following table shows the meaning of each of the colors.

Color	Meaning
None	Empty position (no cup or tube).
Gray	Ready.
Green	All tests have been calculated (but not necessarily validated).
Yellow	Cup or tube is blocked, because a reagent or diluent is missing.
Red	• Cup or tube is empty. • Sample is not known. • Position conflict between two samples. • No sample on this position (adapter is present, but not the cup). • Barcode cannot be read. • Clot detected.

Cassettes tab

Use the Cassettes tab to review the status of each cassette on board.


Status
File View Tools Window Help
Missing & Blocked
Samples
Cassettes
Test Status
Analyzer
ISE
Start
Stop
NH3L
66
In Use
GLUB
63
In Use
GLNB
28
Expired
GLUC3
710
In Use
GLUB
0
Empty
LDHI2
242
In Use
IGG-T
38
In Use
LACT2
17
In Use
CLEAN
Ready
A
B
C
D
2
E
4
F
1
G
H
admin
27/03/2012 18:15
A
B
C
D
E
F
G

A *Cassette name*

B *Number of tests left in the cassette*

C *Cassette status*

D *Slot ID*

E *Rack number*

F *Empty position*

G *Empty slot*

Tips

- The slot IDs are identified by the letters A through H.
- Cassette barcodes are read automatically when you load them.
- To display the details for a cassette, do one of the following:
  - Double-click the cassette.
  - Right-click the cassette, then choose Item Detail.
  - Select the cassette and press Space.
- Use the same techniques to display details for the whole rack, but click the rack number.
- Racks that have been removed from the system are shown as “greyed-out” racks in the Cassettes tab.

  “Loading cassettes” on page B-40

- Press F1 to display Help for this tab.

Color coding on the Cassettes tab

The cassette graphics are color-coded. The following table shows the meaning of each of the colors and the action that should be taken by the user.

Color	Meaning	User action
Green	• New cassette	None
	• Ready	None, the cassette is ready for use.
	• In Use	None.
Yellow	• Cal. expired	Replace the cassette. See “Loading cassettes” on page B-40.
	• Req. Mixing	
	• Near Expiration or Expired	Replace the cassette. See “Loading cassettes” on page B-40.
	• Not enough for worklist or Cassette Tests Low	The number of ordered tests is bigger than the number of tests left in the cassette. The warning threshold defined for the cassette has been reached (Configuration / Cassettes / ID). Load additional cassettes. See “Loading cassettes” on page B-40.
Red	• Empty	Replace the cassette. See “Loading cassettes” on page B-40.
	• Unknown fluid (text shown on Details only)	Definition not loaded. See “About cassette definitions” on page G-15.
	• Conflict with position... (text shown on Details only)	Conflict of positions between cassettes. Remove and re-insert the rack. See “Rack system” on page A-26.

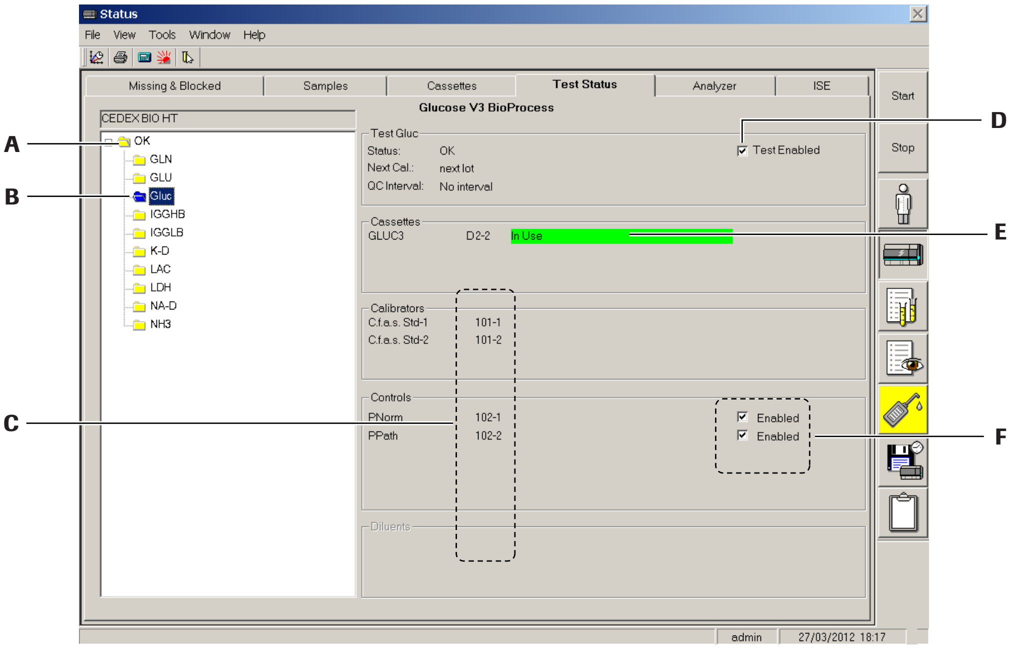
Tip

Cassettes whose barcode cannot be read are not displayed on the Cassettes tab. You see a blinking red LED. Check whether the label is damaged and reinsert the cassette. Make sure the definitions for the cassette are available on the system. You may have to replace the cassette with a new one.

Test Status tab

Use the Test Status tab to review detailed summary information about a test.

The tests are listed in folders based on the current test status: Blocked, Disabled, or OK. This tab also tells you when the next calibration for that test is due.


Status
File
View
Tools
Window
Help
Missing & Blocked
Samples
Cassettes
Test Status
Analyzer
ISE
Start
Stop
CEDEX BIO HT
OK
GLN
GLU
Gluc
IGGHB
IGGLB
K-D
LAC
LDH
NA-D
NH3
Test Gluc
Cassettes
Calibrators
Controls
Diluents
A
B
C
D
E
F

Glucose V3 BioProcess

Status: OK
Next Cal.: next lot
QC Interval: No interval
☑ Test Enabled

GLUC3 D2-2 In Use

C.f.a.s. Std-1 101-1
C.f.a.s. Std-2 101-2

PNorm 102-1 ☑ Enabled
PPath 102-2 ☑ Enabled

admin 27/03/2012 18:17

A *Tests are grouped in folders, depending on their status.*

B *Selected test whose details are displayed on the right.*

C *Slot ID, rack number, and position on the rack.*

D *Enable or disable the selected test.*
Tests may be automatically disabled (Configuration / Result Handling).

E *Status message.*
Red background: Take immediate action.
Yellow background: Warning, take action as soon as possible.

F *Select or clear check boxes to enable or disable individual controls for the selected test. The check boxes are selected by default.*

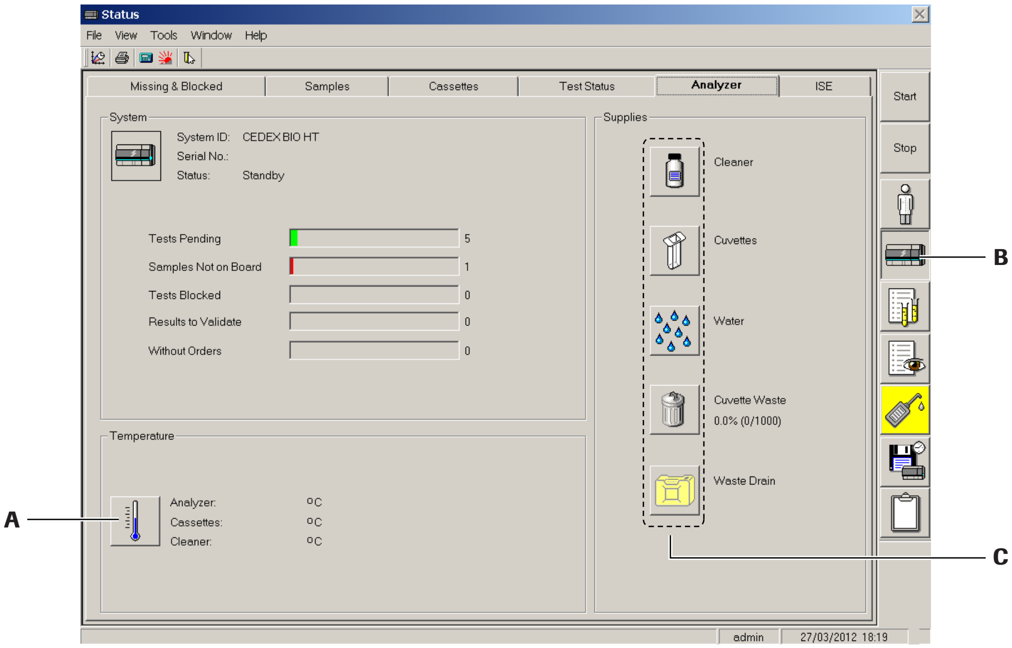
Tips

- Double-click on items in the Cassettes, Calibrators, Controls, and Diluents groups, to display details information on the item.
- Clear the Test Enabled check box to disable a test. Calibrations and controls can be run on disabled tests, but samples cannot.
- You can disable a control temporarily here (but you must re-enable it here also). Use the check box to the right of each control to enable or disable it.
- Next Cal and QC Interval: These are values from the test definition.
- All cassettes associated with the selected test are listed, even if they are not on board.
- The Calibration Postponed status indicates that for the selected test the calibration was due, and that this calibration has been postponed.

- The Clot detected status indicates that a clot was detected.
- If you see, for example, a status of Diluent not on board, and you replace the diluent while the system is in Standby, the values for Status and Next Cal. in the Test group are not updated until the system is in Operating. The information in the Diluents group, however, is updated immediately. You may have to click (Re)Start on the navigation bar to get the system to Operating mode.
- The Diluents group is empty if no diluent is used for the selected test.
- Press F1 to display Help for this tab.

Analyzer tab

Use the Analyzer tab to review the system, that is, the status of tests and orders, temperature, and resources.


Status
File
View
Tools
Window
Help
Missing & Blocked
Samples
Cassettes
Test Status
Analyzer
ISE
Start
Stop
System
Supplies
Temperature
Cleaner
Cuvettes
Water
Cuvette Waste
Waste Drain
A
B
C

System ID: CEDEX BIO HT
Serial No.:
Status: Standby

Tests Pending	5
Samples Not on Board	1
Tests Blocked	0
Results to Validate	0
Without Orders	0

Analyzer: °C
Cassettes: °C
Cleaner: °C

Cuvette Waste 0.0% (0/1000)

admin 27/03/2012 18:19

A *Shows the temperature of the analyzer, cassette area, and cleaner.*
If the temperatures are not within the required limits, the system stops.

B *The icon on the Status button changes depending on the system status (see “System states” on page A-42), and the resource status (see “Resource status” on page B-42).*

C *Check the resource icons:*
The Cleaner icon shows the status of the cleaner fluid bottle.
The Cuvettes icon shows the status of the cuvettes reservoir.
The Water icon shows the status of the water supply.
The Cuvette Waste icon shows the status of the cuvette waste box.
The Waste Drain icon shows the status of the waste drain or reservoir.

The icons are color-coded:
Red = Take action immediately
Yellow = Take action soon
Green or gray = No action needed

Tip

Press F1 to display Help for this tab.

Analyzer tab information

The Analyzer tab contains important information that you should review regularly and whenever the Status button on the navigation bar changes color.

System group

System ID and serial number

The system ID is user-defined in the Configuration work area. The serial number identifies your instrument uniquely and is supplied with the instrument.

Status icon The icon in the top left corner of the tab shows the current status of the instrument.

"System states" on page A-42

Bar graphs indicators The Bar graph indicators show the number of:

- Tests waiting to be run.
- Samples that are not on board.
- Blocked tests (for all, sample, control and calibration orders).
- Results requiring validation.
- Samples loaded that do not have an order associated with them.

Temperature group The temperature of the analyzer (where all the photometric measurements are made), the cassette area and the cleaner is shown.

Supplies group The icons change their background color when the supply is low (yellow), empty or full (red).

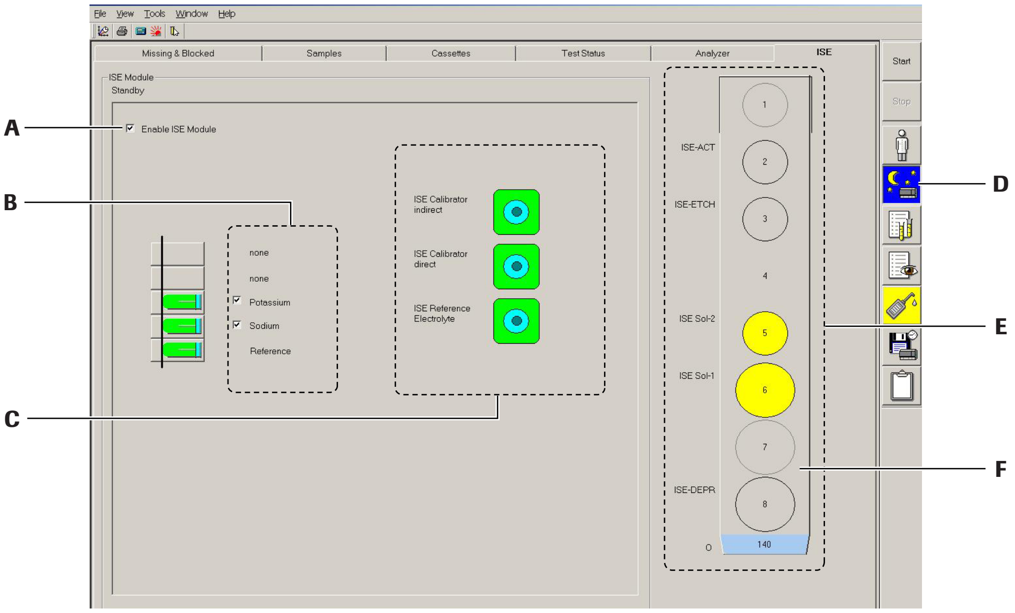
The cuvette waste container counts cuvettes; the count is restarted when you confirm that the cuvette waste container has been emptied.

The system detects when the fluid waste container (waste drain) is removed. When you reinstall the waste container, a message is displayed for you to confirm that you have emptied the container.

"Checking resources" on page B-42

ISE tab

Use the ISE tab to review information about the ISE solutions on the ISE module, the ISE rack, and the installed electrodes.


File
View
Tools
Window
Help
Missing & Blocked
Samples
Cassettes
Test Status
Analyzer
ISE
ISE Module
Standby
☑ Enable ISE Module
none
none
☑ Potassium
☑ Sodium
Reference
ISE Calibrator indirect
ISE Calibrator direct
ISE Reference Electrolyte
ISE-ACT
ISE-ETCH
ISE Sol-2
ISE Sol-1
ISE-DEPR
1
2
3
4
5
6
7
8
O
140
Start
Stop
A
B
C
D
E
F

A *Select or clear this check box to enable or disable the ISE module.*

B *Select or clear these check boxes to enable or disable the ISE electrodes.*

C *Status of ISE solutions on the ISE module.*

D *The icon on the Status button changes depending on the status of the system.*

E *The ISE rack status display.*

F *Double-click to display the status of this item.*

Tips

- If you do not have an ISE module, you must still place bottles of deproteinizer and activator on the ISE rack. You can use the other positions for diluents.
- The positions of the ISE solutions on the ISE rack are not fixed, but Roche recommends to use the predefined positions.

  "Replace ISE solutions on the ISE rack" on page F-32

  These positions are defined using Configuration / Lab / Reserve Positions.
- All ISE solutions on the ISE rack should have caps except for the activator and SDR2.
- If you pull out the ISE rack, a dialog box is displayed when you replace the rack. Use the dialog box to indicate the solutions you have replaced.

  Leave the check boxes cleared for ISE solutions you have not replaced and for special diluents.
- Press F1 to display Help for this tab.

- After replacement and confirmation of the ISE solution and/or diluent bottle on the ISE rack, the appropriate bottle volume is assigned to the defined ISE rack position for the correct volume management.

Displaying item details

To display details for an item in the Status work area, do one of the following:

- Double-click the item.
- Right-click the item and choose Item Detail from the context menu.
- Select the item and press Space.

The corresponding details box is displayed.

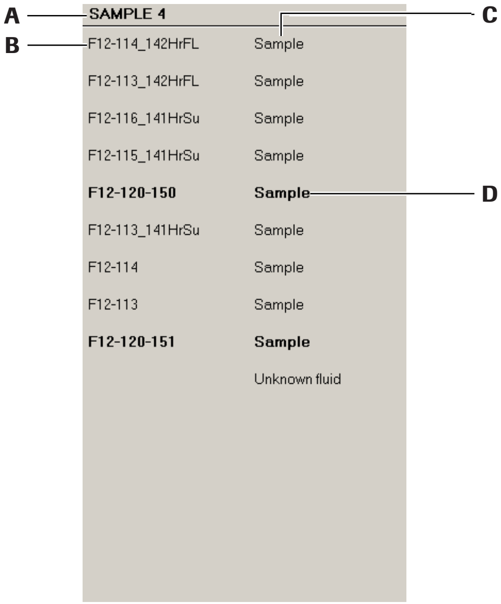
The details box looks similar for the various items. The actual contents depends on the item for which detailed information is displayed.

The following are examples for detailed information.

Sample details Double-click a rack position on the Sample tab or an item on the Missing & Blocked tab to display, for example, the following dialog box.

A *Status of this sample*
B *Slot ID, rack number, and position on the rack*
C *Reasons why this sample is blocked*

Rack details Double-click a rack number on the Samples tab to display the following dialog box.

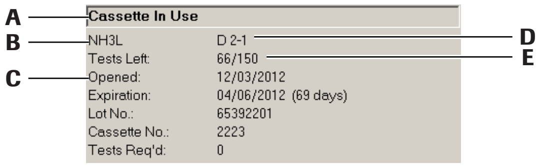


SAMPLE 4

F12-114_142HrFL	Sample
F12-113_142HrFL	Sample
F12-116_141HrSu	Sample
F12-115_141HrSu	Sample
F12-120-150	**Sample**
F12-113_141HrSu	Sample
F12-114	Sample
F12-113	Sample
F12-120-151	**Sample**
	Unknown fluid

A *Rack name (Defined in Configuration / Lab / Racks)*
B *Order number, control name, or calibrator name*
C *Sample type (or other solution)*
D *STAT orders are shown in bold*

Cassette details Double-click a cassette graphic on the Cassettes tab to display the following dialog box.



Cassette In Use

NH3L	D 2-1
Tests Left:	66/150
Opened:	12/03/2012
Expiration:	04/06/2012 (69 days)
Lot No.:	65392201
Cassette No.:	2223
Tests Req'd:	0

A	*Status of this cassette*
B	*Cassette short name*
C	*Date this cassette was opened*
D	*Slot ID, rack number, and position on the rack*
E	*Number of tests remaining and total number of tests*

Tip

The details box for cleaner cassettes looks similar.

Selected tasks

► To review the status of tests on the system

1. Click Status on the navigation bar.
2. Click the Test Status tab.
3. Folders such as Blocked and Disabled are displayed.
4. Click the test.

   The information for the selected test is displayed on the right.

Tip

You can display detailed information on the selected test by double-clicking an entry in the Cassettes, Calibrators, controls, or Diluents group. This displays the detail box for the item selected.

► To enable or disable a test

1. Click Status on the navigation bar.
2. Click the Test Status tab.
3. Click the test.

   The information for the selected test is displayed on the right.
4. Select or clear the Enable Test check box to disable the test.

Tip

You cannot process a sample using a disabled test. You can, however, run calibrations and quality controls even if the test is disabled.

► To enable or disable the ISE module

1. Click Status on the navigation bar.
2. Click the ISE tab.
3. Select or clear the Enable ISE Module check box.

Tip

If you disable the ISE module, you must still place bottles of deproteinizer and activator on the ISE rack. You can use the other positions for diluents.

► To enable or disable ISE electrodes

1. Click Status on the navigation bar.
2. Click the ISE tab.
3. Select or clear the check box to the right of each electrode to enable or disable it.

► To replace ISE solutions on the ISE rack

"Replace ISE solutions on the ISE rack" on page F-32

Orders

Creating, modifying, and reviewing orders

This chapter describes the Orders work area and how to use it. It shows you how to request tests, calibrations, and quality controls.

In this chapter

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  Specifying an order ID B-97
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About orders

An order specifies the tests to be performed on a sample. An order also contains information about the sample and supplementary information about the order (order demographics). Order demographics include information about the order creation date and time.

You can create orders manually in the Orders work area, or your system may download orders automatically from the host system.

The way in which the sample and order information is presented, depends on how your system is configured.

Order IDs

Each order must have an order ID, which may be alphanumeric (for example, AA-1234) or numeric (for example, 1234). Your system may be configured to increment order IDs automatically. This means that a new order ID is automatically displayed when you open the Orders work area (or save the previous order).

Order IDs are valid until they are deleted. Typically, the system is configured to delete processed orders automatically every morning, and with it the order IDs are deleted. You then can use the same order IDs the next day. You can purge orders only when the order has been processed, that is, when the results have been accepted and transmitted to the host, provided you work with a host system.

Racks and sample handling

The way in which you place samples in racks depends on how the racks are configured on your system. Typically, you will define racks for a specific tube type (Configuration / Lab / Racks) and have tubes of one type on the same rack.

Caution

You cannot mix tube sizes on the same rack. For example, you cannot put 5 mL and 7 mL tube types on the same rack.

Orders at a glance

Use the following table to locate specific tasks by work area and tab.

Work area	Tab	Tasks
Status	Missing & Blocked	• Review missing and blocked samples for the current worklist.
	Samples	• Review samples on board; color shows the status. Double-click a rack position to display the details for the selected sample.
Orders	Worklist	• Review the status of active orders and tests. • Access directly the areas where you perform the most frequent tasks on these items, such as editing and validating.
	Sample	• Create an order. • Add tests or profiles to an order. • Modify or delete an order. • Add or modify order information • Assign samples to rack positions. • Request a dilution.
Results	Validate	• Review unaccepted (flagged) results. • Accept results that have not been automatically accepted. • Rerun a test (for example, with dilution). • Monitor results. • Review details and sample rate information for unaccepted results.
	Sample	• Review all results for an order whether accepted or not. • List results by order date and order ID. • Select results for specific orders, dates, and STAT or non-STAT samples. • Review statistics on a specific test.

Use the following table to locate specific tasks in the Configuration work area:

Icon	Tab	Tasks
General	Barcode	- Specify barcode use.
Lab	Sample Tubes	- Specify tube parameters. - Specify Cup on Tube parameters.
	Racks	- Specify rack configuration: define rack groups, rack numbers, and assign tube type.
	Reserve Positions	- Preassign cup and tube positions for ISE solutions, diluents, calibrators and controls.
Database	Automatic Actions	- Specify Start Order ID, to enable automatic order numbering and automatic assigning of samples to rack positions.
	Demographics	- Predefine the comments for up to three comment boxes in order demographics.

Orders work area

To access the Orders work area, click the Orders button on the navigation bar.

The Orders work area has the following four tabs:

Tab	Function
Worklist	This tab gives a clear and comprehensive overview of the active orders and tests, and provides easy access to the tasks you perform most frequently on these items, such as editing and validating.
Sample	This tab allows you to: • Request tests for a sample by creating an order. • Request dilutions. • Create multiple copies of an order. • Give an order STAT priority.
Calibration	This tab allows you to request calibrations for specific tests.
Quality Control	This tab allows you to request quality controls for specific tests.

Context menu

You can right-click a test, order, calibration, or control in any tab to display the context menu. It contains one or more of the following frequently used commands:

Menu item	Function
Clear	Clears the text boxes.
Copy	Copy to the clipboard text that was selected in a box.
Copy Order	Copy the details of the current order to the clipboard. Use with the Paste Order command to create multiple orders with the same content.
Cut	Cut selected text from a box.
Delete	Deletes the selected item.
Delete Order	Deletes the current order.
Detail	Gives detailed information for the selected item; for example, for a test, the on-board cassettes are listed.
Dilutions	Request a dilution for the selected test.
Edit	On the Worklist tab, access the Sample tab to edit the item.
Multiple Tests	Request the same test multiple times for the order.

Menu item	Function
Paste	Paste previously selected text into a box.
Paste Order	Paste the details of an order into the current order. (You must have previously saved the details of another order and used Copy Order.)
Paste Multiple	Create multiple copies of an order. You copy tests from an existing order and then use the Paste Multiple dialog box to create a set of orders based on these tests.
Postpone Calibration	Overrule a system request for calibration and postpone it by a certain period of time or an event.
Reset	Resets the text boxes.
Sample Handling	Review the rack numbers and rack positions for the selected sample.
Select All	Selects all text in a box.
Undo	Revokes the last action.
Use Last Order	Re-displays the details of the last order you used.
Validate	On the Worklist tab, access the Validate tab on the Results work area to validate the result(s) of the selected item.

Worklist tab

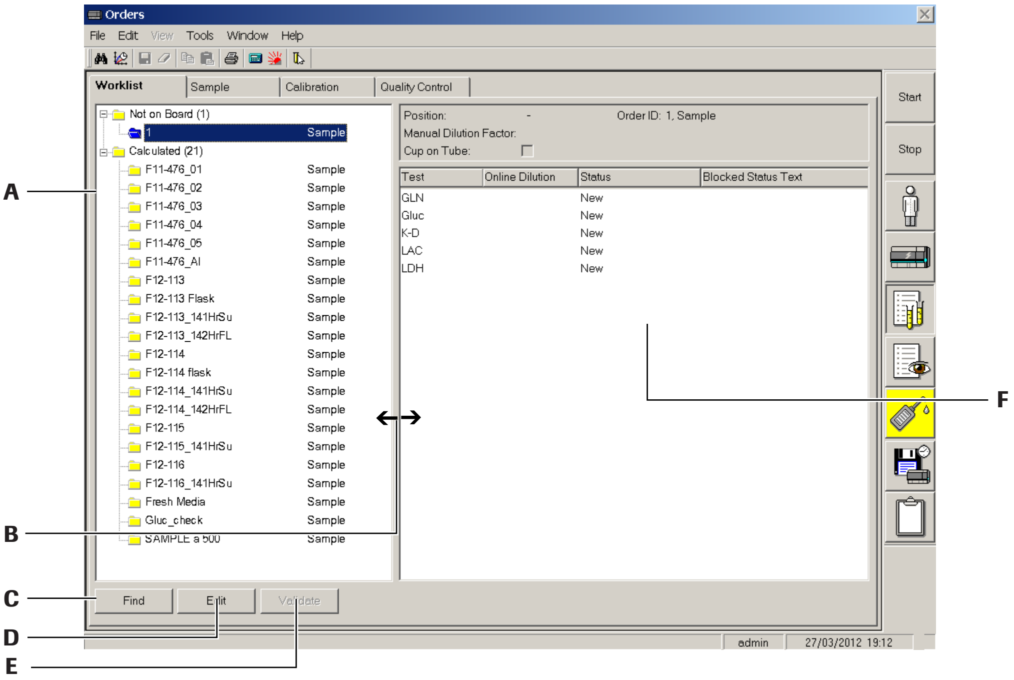
Use the Worklist tab to get a clear and comprehensive overview of the active orders and tests, and to gain easy access to the tasks you perform most frequently on these items, such as editing and validating.

The Worklist tab provides maximum support to users who work without barcodes and who are not connected to a host system.

The tab is divided into two horizontally adjustable areas:

- The area on the left, the Orders list, contains the folder view of the sample, calibration, and control orders.

The area on the right, the samples and tests list, displays detailed information on the item that is selected in the Orders list.



Not on Board (1)
1 Sample
Calculated (21)
F11-476_01 Sample
F11-476_02 Sample
F11-476_03 Sample
F11-476_04 Sample
F11-476_05 Sample
F11-476_AI Sample
F12-113 Sample
F12-113 Flask Sample
F12-113_141HrSu Sample
F12-113_142HrFL Sample
F12-114 Sample
F12-114 flask Sample
F12-114_141HrSu Sample
F12-114_142HrFL Sample
F12-115 Sample
F12-115_141HrSu Sample
F12-116 Sample
F12-116_141HrSu Sample
Fresh Media Sample
Gluc_check Sample
SAMPLE a 500 Sample

Position: -
Order ID: 1, Sample
Manual Dilution Factor:
Cup on Tube: ☐

Test	Online Dilution	Status	Blocked Status Text
GLN		New	
Gluc		New	
K-D		New	
LAC		New	
LDH		New	

A *Orders list, see section below.*

B *Adjust the width of the Order list to display all information.*

C *Click Find to search for a specific order ID.*

D *Click Edit to access the appropriate tab, where you can edit the order. This function is only available if there are related data on the system.*

E *Click Validate to access the Validate tab of the Results work area, where you can validate the results. This function is only available if the selected order has test results that need validating.*

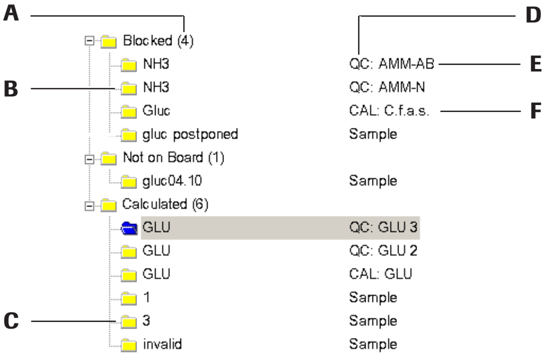
F *The information displayed in the samples and tests list depends on the type of the selected order (sample, calibration, control), and on the folder the selected order is placed in. The samples and tests list provides a good overview of the status of the selected sample, calibration, or control order.*

Tip

- Press F1 to display Help for this tab.

Orders list on the Worklist tab

This area contains the folder view of the sample, calibration, and control orders:



Blocked (4)	
NH3	QC: AMM-AB
NH3	QC: AMM-N
Gluc	CAL: C.f.a.s.
gluc postponed	Sample
Not on Board (1)	
gluc04.10	Sample
Calculated (6)	
GLU	QC: GLU 3
GLU	QC: GLU 2
GLU	CAL: GLU
1	Sample
3	Sample
invalid	Sample

A *Number of entries in the folder. This number is automatically updated. An increase of the number, for example, points to new entries.*

B *Test name*

C *Order ID*

D *Kind of order (calibration, quality control or sample type)*

E *Control name. With quality control orders, the control name is displayed.*

F *Calibrator name. With calibration orders, the calibrator name is displayed.*

The Orders list may contain the following folders and information:

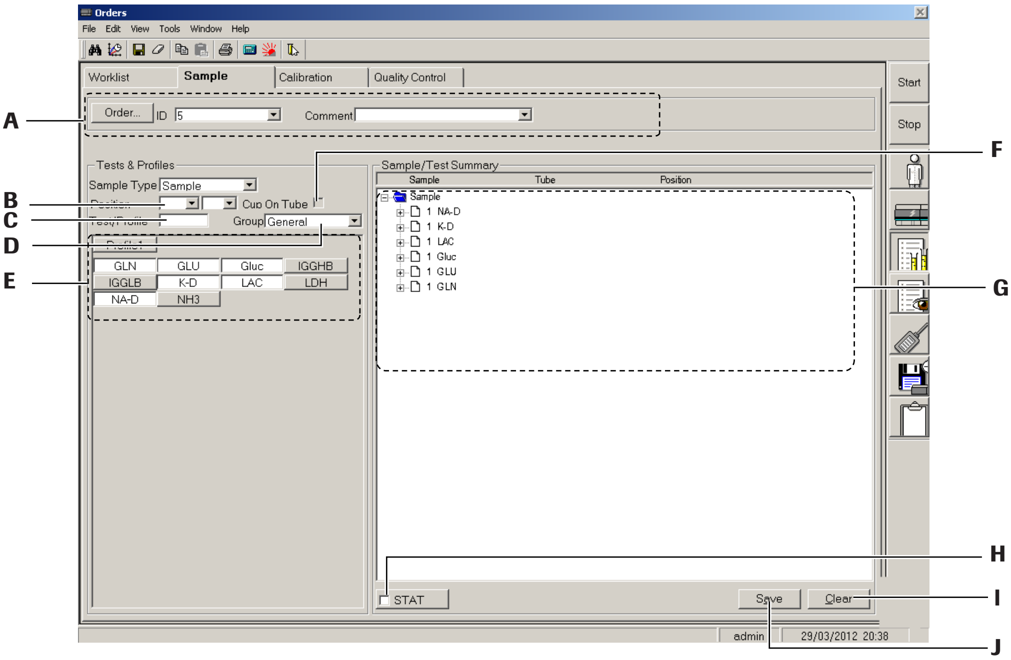
Folder	Contents
Blocked	Orders with at least one test with the Blocked status.
Not On Board	Orders for which there are still tests to be performed, and for which the sample is not on board the system.
Without Orders	Samples without orders.
Calculated	Orders with calculated results.
New	Orders with tests that still need to be performed.
Running	Orders with tests that are currently being performed.

Tips

- Only folders that contain entries are displayed in the Orders list.
- STAT orders are displayed in bold print.
- To follow the logical job sequence, work through the entries in the list from top to bottom.

Sample tab

Use the Sample tab to create, modify, review, or delete an order for tests. You can select individual tests, or a profile containing several tests.



ID: 5

Sample Type: Sample

Group: General

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Orders
File Edit View Tools Window Help
Worklist
Sample
Calibration
Quality Control
Start
Stop
Order...
Comment
Tests & Profiles
Position
Test/Profile
Cup On Tube
Profile 1
GLN
GLU
Gluc
IGGHB
IGGLB
K-D
LAC
LDH
NA-D
NH3
Sample/Test Summary
Sample
Tube
Position
1 NA-D
1 K-D
1 LAC
1 Gluc
1 GLU
1 GLN
STAT
Save
Clear
A
B
C
D
E
F
G
H
I
J

A *Use to display or specify order details if you are creating a new order or modifying an existing one.*

B *To manually assign a sample to a rack position, first select a rack from the first drop-down list, and then select an available rack position from the second drop-down list.*

C *Type a test name, a profile name or a test number, and then press Enter. The specified tests are added to the Sample/Test summary group. Alternatively, you can use the test and profile buttons.*

D *Select a test group to customize the type and number of test buttons displayed. Each test can belong to one or more groups, depending on the configuration of your system. When you specify the name of a group in the Group box, only buttons for tests that belong to that group are displayed.*

E *Click one or more of the profile and test buttons to select the tests for the order you are creating. For tests only, you can remove a test from an order by clicking the corresponding button a second time. Use the scroll bars to display more tests, if necessary. Use the Group list to select a predefined group of tests, for example all STAT tests. Test groups are only available if they were previously defined in Configuration / Definition / Test).*

F *Select the Cup on Tube check box to indicate that you want to use the predefined secondary cup on top of the primary tube for the selected sample type. This option is only available if a sample type other than Automatic is selected.*

G *The Sample/Test Summary group lists the tests selected for the current order.*

H *Select this check box to give the order STAT priority.*

I *Click Clear to clear the boxes in the tab.*

J *Click Save to save the current order.*

Tips

- To request a dilution, double-click a test name to open the Dilutions dialog box, or right-click a test name and choose Dilutions in the context menu.

  “Requesting a dilution” on page B-107

- To review the results of completed orders, use the Sample tab in the Results work area.
- To review flagged results, use the Validate tab in the Results work area.

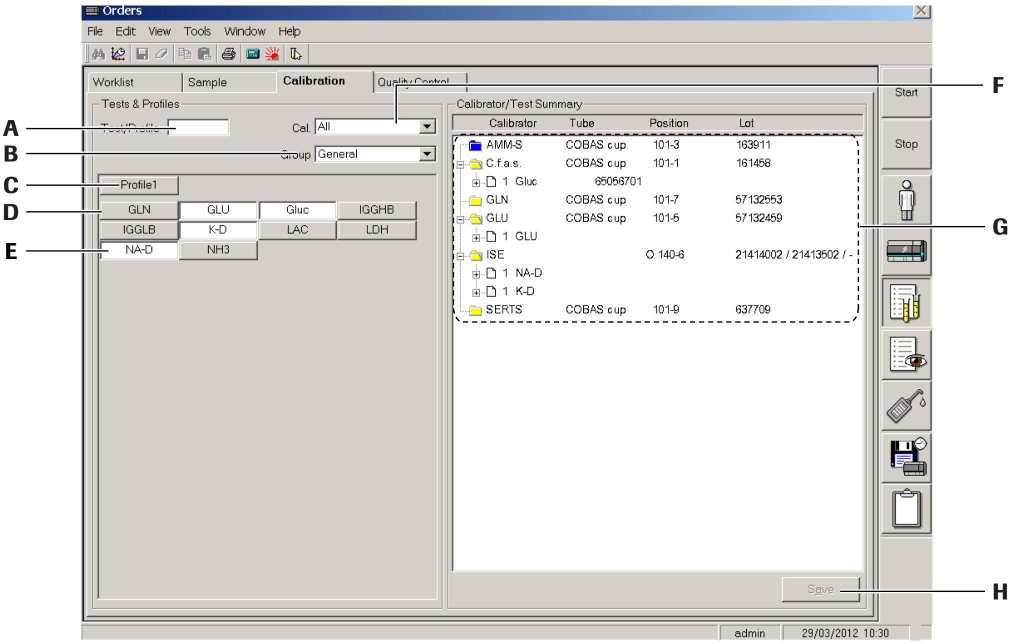
“Working with Orders” on page B-102

- The system can handle up to 1000 test requests at any one time. If you request more, the system will accept 1000 tests and issue a message.
- Press F1 to display Help for this tab.

Calibration tab

Use the Calibration tab to create, modify, postpone, review, or delete calibration requests on one or more tests.

You can select individual tests, or a profile containing several tests. All pending calibrations, whether requested manually or scheduled automatically by the system, are listed.


Orders
File
Edit
View
Tools
Window
Help
Worklist
Sample
Calibration
Quality Control
Tests & Profiles
Test/Profile
Cal.
All
Group
General
Profile1
GLN
GLU
Gluc
IGGHB
IGGLB
K-D
LAC
LDH
NA-D
NH3
Calibrator/Test Summary
Start
Stop
Save
admin
29/03/2012 10:30
A
B
C
D
E
F
G
H

Calibrator	Tube	Position	Lot
AMM-S	COBAS cup	101-3	163911
C.f.a.s.	COBAS cup	101-1	161458
1 Gluc	65056701		
GLN	COBAS cup	101-7	57132553
GLU	COBAS cup	101-5	57132459
1 GLU			
ISE		O 140-6	21414002 / 21413502 / -
1 NA-D			
1 K-D			
SERTS	COBAS cup	101-9	637709

A *You can select a test or profile for the calibration request by typing its name or number here.*

B *In the Configuration work area, tests can be assigned to groups. You can use this feature to reduce the number of test buttons displayed at one time. Select another group if you do not see the required test.*

C *Click a profile button to request calibrations for all tests in the profile.*

D *Click test buttons to request a calibration for the test.*

E *Calibration already requested for this test.*

F *Select a calibrator to display only the tests that are associated with the calibrator.*

G *The Calibrator/Test Summary lists all current requests for calibrations.*

H *Click Save to save the calibration request.*

Tips

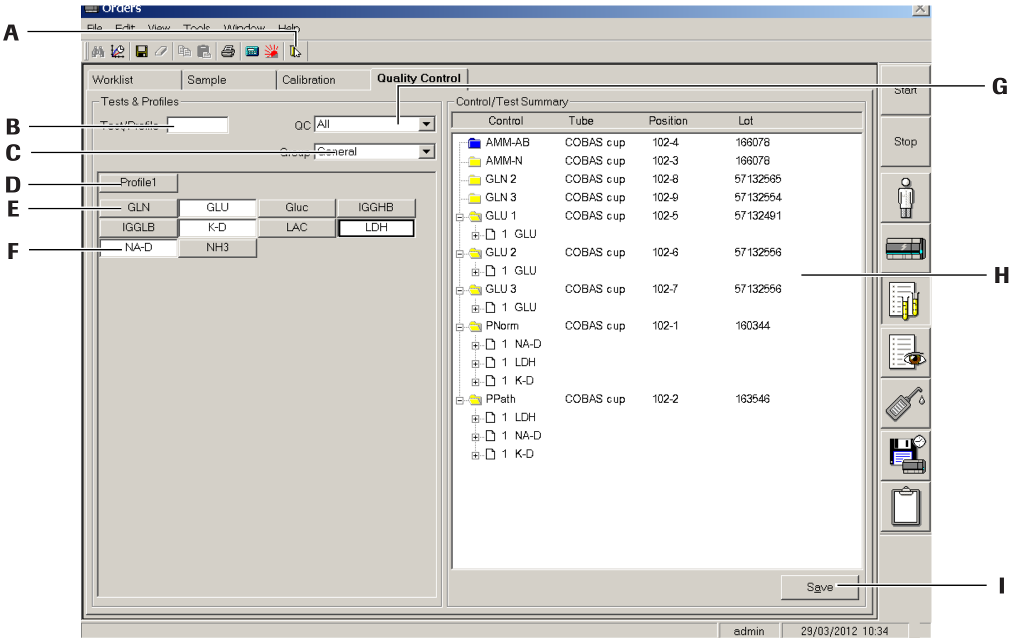
- When you request a calibration for a test that has more than one cassette on board, the Calibrate dialog box is displayed. Select the cassette that you want to use.
- To postpone a calibration, right-click the test that now requires a calibration and choose Postpone Calibration from the context menu.
- To review completed calibrations, use the Calibration tab in the Results work area.
- To review flagged calibrations, use the Validate tab in the Results work area.
- Press F1 to display Help for this tab.

For more information, see Chapter 10, “Calibration”

Quality Control tab

Use the Quality Control tab to create, modify, review, or delete requests for quality control measurements.

You can select individual tests, or a profile containing several tests. All pending controls, whether requested manually or scheduled automatically by the system, are listed.



QC: All

Group: General

Control/Test Summary

Control	Tube	Position	Lot
AMM-AB	COBAS cup	102-4	166078
AMM-N	COBAS cup	102-3	166078
GLN 2	COBAS cup	102-8	57132565
GLN 3	COBAS cup	102-9	57132554
GLU 1	COBAS cup	102-5	57132491
1 GLU			
GLU 2	COBAS cup	102-6	57132556
1 GLU			
GLU 3	COBAS cup	102-7	57132556
1 GLU			
PNorm	COBAS cup	102-1	160344
1 NA-D			
1 LDH			
1 K-D			
PPath	COBAS cup	102-2	163546
1 LDH			
1 NA-D			
1 K-D			

admin 29/03/2012 10:34

A *Click the Place Item button to place samples on the rack while defining orders for samples whose barcode could not be read, especially if you work with a host system.*

B *You can select a test or profile for the quality control request by typing in its name or number here.*

C *In the Configuration work area, tests can be assigned to groups. You can use this feature to reduce the number of test buttons displayed at one time. Select another group if you do not see the required test.*

D *Click a profile button to request controls for all tests in the profile.*

E *A control request has been made for this test.*

F *Click test buttons to request a control for the test.*

G *If you select a control here, only the tests that are associated with the control are displayed.*

H *The Controls/Test Summary lists all current requests for controls.*

I *Click Save to save the quality control request.*

Tips

- To review completed or flagged controls, use the Quality Control tab or the Validate tab respectively in the Results work area.
- Press F1 to display Help for this tab.

For more information, see Chapter 11, “Quality controls”.

Creating an order

To run tests on samples, you must create an order with a unique order ID. The order specifies which tests are to be run and other optional information about the order and the sample.

You can create a new order, or you can add tests to an existing order.

When you create an order manually, you have to work through a series of substeps:

1. Specify an order ID (mandatory) and demographics.
2. Select tests for the order and save.
3. If there are no barcodes on the tubes and you work without a host system, you must assign the samples to rack positions. This can be done either automatically or manually. (See "Assigning samples to racks" on page B-96.)

These and other step-by-step procedures related to the Orders work area are described in this section.

Some procedures may differ depending on the lab setup you are working with. The main criteria are whether or not you work with barcodes and whether or not you work with a host system.

The procedures describing the various steps of creating an order apply to working without barcodes and without host system, unless otherwise indicated.

For information on the procedures when working with a specific lab setup, see the Daily routine sections in Chapter 5, "Daily workflow".

Some of the most common problems in connection with creating orders are dealt with in "What if?" on page B-101.

Specifying an order ID

You can enable the automatic order numbering facility in Configuration / Database / Automatic Actions. If it is enabled, the order ID increases automatically when you open the Sample tab in the Orders work area. This ensures that you always have a unique order ID. You can accept the order ID or type over it.

The automatic order numbering facility is not available for alphanumeric order IDs.

► To specify an order ID

1 Click Orders on the navigation bar.

2 Click the Sample tab.

3 Type a valid order ID in the ID box or use the proposed order ID.

4 Click the Order button.

The Order Demographics dialog box is displayed.

5 Add information as required.

6 Click OK.

Tips

- Step 3: A valid order ID has up to 15 alphanumeric characters.
- Step 3: Users who work with barcodes first insert the sample rack into the system. All samples without test orders are then available in the ID drop-down list. Select an entry from this list.

- Your system can be set up to automatically purge order IDs at BOD. You can then reuse order IDs each day.

  "Purging and deleting orders" on page B-109

- Step 5: Comments in the Order Demographics dialog box are defined in Configuration / Database / Demographics.

Selecting tests for the order

You can add tests one at a time, or you can select a test profile.

► To add tests to an order

In the Sample tab in the Orders work area:

1. Click the required profile buttons.
2. Click the required test buttons.
3. Click Save.

Tips

- The buttons for profiles are listed above those for individual tests.
- Selected tests are shown in white and listed in the Sample/Test Summary group.
- If a test belongs to two profiles and both profiles are selected, the test is only run once.
- You can also select a test or profile by typing its name in the Test/Profile box.

Assigning samples to racks

In some cases, for example if you do not use barcodes, or when a sample barcode could not be read, you must assign each sample to a specific position on a rack. You can do this in two ways:

- Use the Automatically Assign Rack Position function to automatically assign samples to rack positions.

  Roche recommends using this method if you work with non-barcoded samples.

- Manually assign samples to racks, using either
  - Sample Handling dialog box

    Use this method if you prefer to create an order and then specify all the sample positions for that order before moving on to the next order.

  - Place Items dialog box

    Use this method if you want to assign all the samples on a rack at one go.

Automatically assigning samples to rack positions

► To create an order, using Automatically Assign Rack Positions

1. Define the order ID and demographics.

   The sample type Automatic is displayed, and the Position boxes are disabled.

2. Select tests for the order.
3. Click Save.

   The Sample Handling dialog box is displayed.

See “Sample Handling dialog box” on page B-99.

4 Confirm the automatically assigned rack number and position, or modify them, if required.

Tips

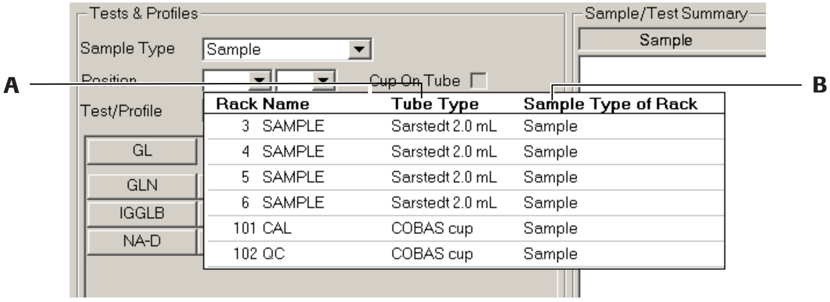
- To enable this function, use Configuration / Database, and select the Automatically Assign Rack Positions box on the Automatic Actions tab.
- Automatic rack position assignment *assigns positions of racks that are not on board the system.*
- You need to define manually the first position for each sample type. This is typically position 1 on the first rack allocated to the sample type in question. All further position assignment for samples of this type will be done automatically.
- Automatic rack position assignment works for samples, not for calibrations or controls.
- Automatic rack position assignment also works when Paste Multiple is used (File > Copy, then File > Paste Multiple). Note that the racks must not be on board, and that the Sample Handling dialog box is not opened automatically.
- Automatic rack position assignment continues as long as there are free positions on racks that are allocated to the sample and tube type of the kind required by your order.
- Roche recommends working with the “Reset Rack Positions at Begin of Day” function (Configuration / Database). This function resets each day the starting positions for automatic placement, as part of the Begin of Day actions.
- When working *with* barcodes, the Automatically Assign Rack Position function must be *dis*abled. To disable this function, use Configuration / Database, and clear the Automatically Assign Rack Positions check box on the Automatic Actions tab.

Manually assigning samples to rack positions

► To assign a sample manually

1 From the Sample Type list, select a sample type other than Automatic.

If you select a sample type other than Automatic, drop-down lists assist you in assigning the sample to a rack position. These lists contain the available rack numbers and positions.



Rack Name	Tube Type	Sample Type of Rack
3 SAMPLE	Sarstedt 2.0 mL	Sample
4 SAMPLE	Sarstedt 2.0 mL	Sample
5 SAMPLE	Sarstedt 2.0 mL	Sample
6 SAMPLE	Sarstedt 2.0 mL	Sample
101 CAL	COBAS cup	Sample
102 QC	COBAS cup	Sample

A *There is a default tube type assigned to each rack.*

B *Sample types that are assigned to a rack are displayed.*

2 Select a rack number from the first Position list.

Once a rack number is selected, you can display the available rack positions in the second list.

3 Select the rack position from the second Position list.

Tips

- A padlock symbol in front of an entry in the first Position list signifies that the rack is on board. With on-board racks, you are alerted by a message if you try to assign a sample to a position you cannot use.
- Use this method to create an order and then specify all the sample positions for that order before moving on to the next order.

► To assign a sample manually, using Sample Handling

1 Click Orders on the navigation bar.

2 Click the Sample tab.

3 Type the order ID in the ID box and press Tab.

4 Choose View > Sample Handling.

The Sample Handling dialog box is displayed.

See “Sample Handling dialog box” on page B-99.

5 Specify the rack number and the position on the rack.

6 Click OK.

7 Put the samples in the correct positions on the rack and load the rack.

Tips

- Normally, you can assign positions only to racks that are not on board.
- Step 5: If the rack is not on board, you can overwrite rack positions.
- Step 5: If the rack position you want to use is not available, choose Tools > Place Items, and click Clear to clear previously assigned rack positions.

► To assign a sample manually, using the Place Items dialog box

1 Click Place Items in the toolbar.

2 Select a rack from the list.

See C below.

3 Click ⊞ to expand the Samples folder.

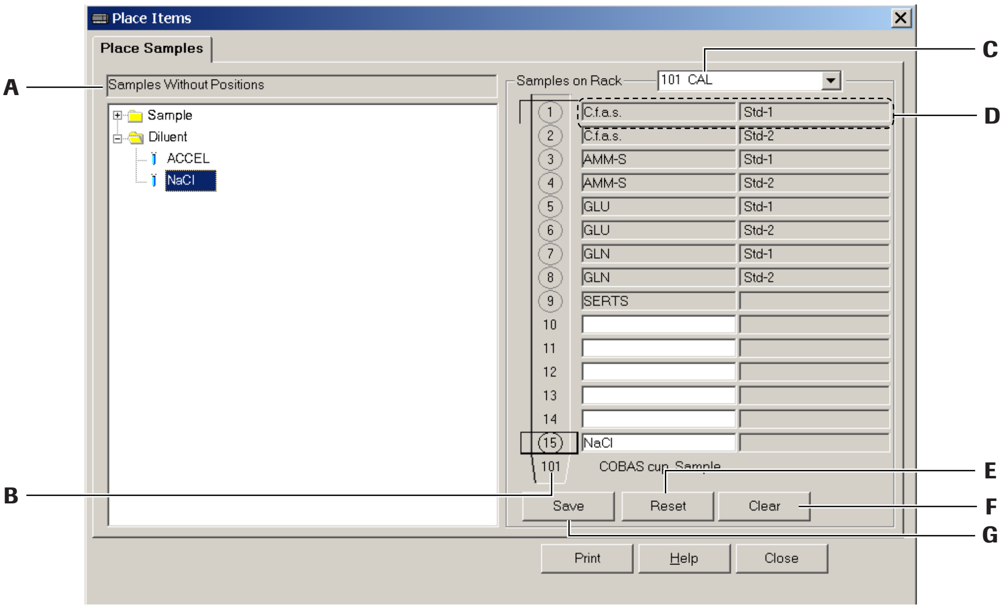
See A below.

4 Drag and drop items from the Samples folder to the rack graphic. The positions you choose must correspond to the actual placement of the samples on the rack.

5 Repeat step 4 for any other samples.

6 Click Save.

7 Place the samples on the correct positions on the rack, and load the rack.


Place Items
Place Samples
Samples Without Positions
Sample
Diluent
ACCEL
NaCl
Samples on Rack
101 CAL
Save
Reset
Clear
Print
Help
Close
A
B
C
D
E
F
G

1	C.f.a.s.	Std-1
2	C.f.a.s.	Std-2
3	AMM-S	Std-1
4	AMM-S	Std-2
5	GLU	Std-1
6	GLU	Std-2
7	GLN	Std-1
8	GLN	Std-2
9	SERTS	
10		
11		
12		
13		
14		
15	NaCl	

101 COBAS cup Sample

A *The Sample folder containing samples to be placed on racks. Click ⊞ to expand or ⊟ to contract the folders.*

B *Rack placement graphic.*

C *Rack identification list.*
Click the arrow to display a list of available racks. The padlock symbol means the rack is on board.

D *Order ID and sample type (or name for other solutions).*

E *Reset the assignments on this rack to what they were when (1) you opened this dialog box or (2) you last saved.*

F *Click Clear to clear all assignments on this rack.*

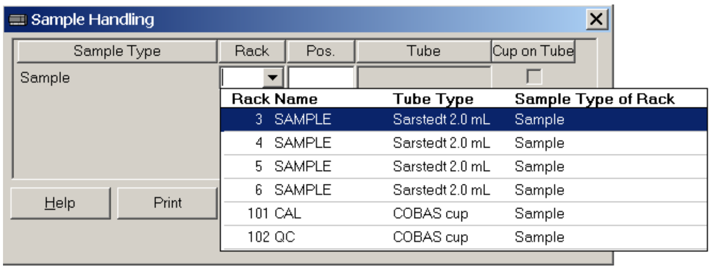
G *Click Save to save the new assignments.*

Tips

- You can assign positions to both on-board and off-board racks.
- Step 2: Click Clear to clear previously assigned rack positions if necessary.
- Step 7: You can print out the sample positions by:
  - Clicking Print in the Place Items dialog box.
  - Choosing File > Print Report > Loadlist.

Sample Handling dialog box

The Sample Handling dialog box serves to assign samples to rack positions, and to confirm rack positions that were automatically assigned. It also serves to enable the Cup on Tube function.


Sample Handling
Help
Print

Sample Type	Rack	Pos.	Tube	Cup on Tube
Sample				☐

Rack Name	Tube Type	Sample Type of Rack
3 SAMPLE	Sarstedt 2.0 mL	Sample
4 SAMPLE	Sarstedt 2.0 mL	Sample
5 SAMPLE	Sarstedt 2.0 mL	Sample
6 SAMPLE	Sarstedt 2.0 mL	Sample
101 CAL	COBAS cup	Sample
102 QC	COBAS cup	Sample

You can display the Sample Handling dialog box at any time by right-clicking a sample or a test in the Sample/Test Summary group and then choosing Sample Handling from the context menu. You can also choose View > Sample Handling from the menu bar when an item is selected.

You cannot change the tube type in this dialog box.

If you do not work with barcodes, the Sample Handling dialog box is automatically displayed when you click Save. If you work with barcodes, the Sample Handling dialog box is not displayed when you click Save.

Tips

- While working with barcodes, you cannot change positions that were fully identified with order ID and sample type, as long as the associated rack is on board.
- You can overwrite positions of racks that are not on board the system without previously having cleared the position, for example on the Place Items dialog box.
- A padlock symbol in front of an entry in the Rack list signifies that the rack is on board. With on-board racks, you are alerted by a message if you try to assign a sample to a position that is not free.
- Assume you work with barcodes, and you have created an order while the rack was not on board, and then you insert the rack. If the system detects a discrepancy between the rack position you defined and the position read from the barcode, the Sample Handling dialog box is displayed. It contains the rack position read from the barcode.
- Changes in the system while the Sample Handling dialog box is displayed, such as inserting a rack, are not automatically reflected on the open Sample Handling dialog box. Close and re-display the Sample Handling dialog box to see the changes in the Rack and Position lists.
- You can print the Sample Handling dialog box.

Selecting Cup on Tube

You can define *one* cup - the Cup on Tube - as the secondary cup you want to use on top of primary tubes (Configuration / System / Lab / Sample Tubes / Cup on Tube).

Tip

You cannot enable Cup on Tube using the Place Items function.

► To enable Cup on Tube while working with barcodes

1. Remove the sample rack from the system.
2. On the Sample tab of the Orders work area, type the Order ID (barcode number) and, if necessary, select the tests.
3. In the Tests & Profiles group, select the sample type from the Sample Type list.
4. In the Tests & Profiles group, select the Cup On Tube check box. This option is only available if the default tube type for the rack allows the use of cups on these tubes.
5. Click Save.
6. Re-insert the sample rack into the system.

Tip

When working with a host system, you first insert the sample rack into the system, and the host sends the orders. You then follow the standard procedure.

► To enable Cup on Tube while working without barcodes

The procedure for enabling Cup on Tube is basically the same as when working with barcodes. The difference is that you select the Cup on Tube check box on the Sample Handling dialog box rather than in the Tests & Profiles group.

1. Remove the sample rack from the system.
2. On the Sample tab of the Orders work area, create the sample order and, if necessary, select the tests.
3. On the Sample Handling dialog box, select the Cup on Tube check box, and click OK.
4. Re-insert the sample rack into the system.

Caution

Re-inserting the rack before having selected and saved Cup On Tube, may lead to serious damage to the probes.

What if?

An order with the same order ID already exists	Order IDs must be unique, so you have to specify an order ID that does not already exist. However, you can use the same order ID if the orders were made on separate days or if the order IDs have been purged.
I can't find the test I need on the buttons	Try selecting another group (Group box) or typing in the name of the test or profile (Test/Profile box). Alternatively, if the test is not installed, contact your system supervisor to see if this test can be made available.
I see predefined order IDs when I open the Samples tab	The automatic order numbering facility is enabled. This means that each time you create an order, the number is automatically increased for the next order. You can manually type over the suggested order ID, if you prefer.

Working with Orders

When you have created an order, you can perform the following operations in the Orders work area:

- Look up orders.
- Review the tests in an order.
- Add tests to an existing order.
- Copy tests from one order to another.
- Make multiple copies of an order.
- Request a dilution.
- Delete tests.
- Delete orders.

These operations are described in the following sections.

Finding orders

You can choose between two methods of finding certain orders:

- With the Lookup function, you type the search criteria directly in boxes on the Sample tab.
- With the Find function, you first start the function by clicking on the toolbar and then type your criteria in the Find Orders dialog box. This method offers more elaborate search criteria.

Specifying search criteria

You can use a wildcard (? or *) in your search, where ? represents a single character, and * represents one or more characters.

If you type	In this box	You find these values
*	Order ID	All values.
77*	Order ID	All values beginning with “77” including: 77, 775, 7756152, 773A21
77?	Order ID	All values beginning with 77, and which have three characters, including: 77, 775, 776, 77A, 77B
Glu*	Name	Gluc, Glut
Glu?	Name	Glut Gluc
5553*	Order ID	55531, 55532, 55534, 555311111012.
555?1	Order ID	55531, 55541, 55581

Tips

- You can only use the * wildcard at the end of a search string. For example, *77, 7*7 are not valid.

- You can specify only one wildcard in a string. For example, 77*? and 5??1 are not valid.

Lookup function

Use the Lookup function for a quick search for the tests of a certain order.

► To look up an existing order

1 Type "*" (asterisk) in the Order ID box, and press Enter.

The Lookup dialog box is displayed, containing a list with all order IDs stored on the system.

2 Select the desired entry and click OK.

The data for the selected order is displayed on the Sample tab.

Find function

With the Find function, you can search for orders by giving an order ID. You can also specify a range of dates within which the order was created.

Accessing the Find function

There are several methods of accessing the Find function:

- Click 🔍 on the toolbar.
- Click Find on the tab.
- Press F3 on the keyboard.

The Find function is available on the Worklist and Sample tabs of the Orders work area, and also on the Validate and Sample tabs of the Results work area.

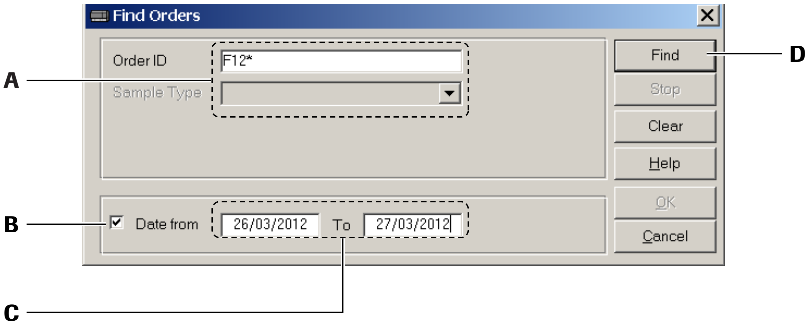
► To find an existing sample or order

1 Click Orders on the navigation bar.

2 Click the Sample tab.

3 Click 🔍 on the toolbar.

The Find Orders dialog box is displayed.



Order ID F12*

☑ Date from 26/03/2012 To 27/03/2012

A *Enter text and wildcards.*

B *Specify a date range for the order.*

C *Specify the start and end dates for the search period.*

D *Start the search, but leave the dialog box open.*

4 Type your search criteria in the Find Orders dialog box.

5 Click Find.

The orders that match the search criteria are listed.

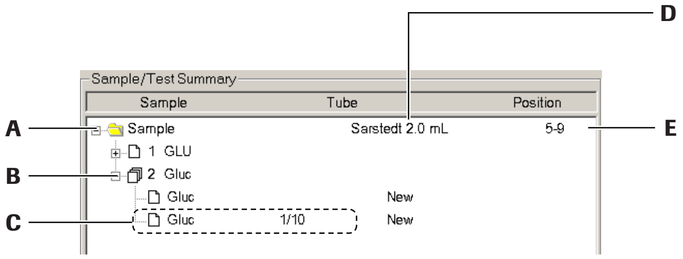
6 Double-click the order that you want to work with.

Tips

- Be aware, that the find function is case-sensitive.
- If the search is not successful, remove or relax some of the search conditions.
- Use the Sounds Like facility to match sounds rather than spellings (English language versions only).

Reviewing tests in an order

The Sample/Test Summary group displays the details of the tests selected for the current order. The tests are displayed in folders and are sorted by their short name; the folders are listed by sample type.



Sample/Test Summary

Sample		Tube	Position
Sample		Sarstedt 2.0 mL	5-9
1 GLU			
2 Gluc			
Gluc		New	
Gluc	1/10	New	

A *Sample type is given by the folder name. Click ⊞ to expand a folder, or ⊟ to collapse it.*

B *A duplicate has been ordered for this test. You can order multiple tests so that you can run a variety of dilutions, for example. The Multiple Tests function is available for sample tests only.*

C *Single test ordered with dilution.*

D *Default tube type.*

E *Position of the sample on the rack.*

- **Tips**Double-click a test line to open the Dilutions dialog box (to request dilutions).

  "Requesting a dilution" on page B-107

- Rack number information is available when:
  - The sample is on board and has been identified by its barcode.
  - The rack position for the sample has been manually assigned.
- Click Save to save any changes that you have made to the order.

Adding tests to an existing order

When you have created and saved an order, you can open it at a later stage and add more tests.

► To add tests to an existing order

1 Click Orders on the navigation bar.

2 Click the Sample tab.

3 Type the order ID in the ID box.

4 Press Tab.

The background in the ID box is grayed out so that you cannot alter the order ID.

5 Click the required profile buttons.

6 Click the required test button.

7 Click Save to save the order.

Tip

You can add tests to a completed order.

Copying data from orders and tests

You can copy a set of tests from one order to another, or from one order to several others.

► To copy tests from one order to another

1. Click Orders on the navigation bar.
2. Click the Sample tab.
3. Display an existing order that contains the tests to be copied.
4. Right-click anywhere in the Sample/Test Summary and choose Copy Order from the context menu.
5. Click Save to save the order.
6. Click Clear to clear the text boxes.
7. Type a new order ID in the ID box. This is the order to which the tests will be copied.
8. Right-click anywhere in the Sample/Test Summary and choose Paste from the context menu.

   The tests are displayed in the Sample/Test Summary group.
9. Add order demographics as required.
10. Click Save.

Tips

- You can modify the new order as required.
- Step 4: You can also choose Edit > Copy.
- Step 8: You can also choose Edit > Paste.

► To create multiple copies of an order

1. Click Orders on the navigation bar.
2. Click the Sample tab.
3. Create an order containing the tests to be copied.
4. Right-click anywhere in the Sample/Test Summary and choose Copy from the context menu.
5. Click Save to save the order.
6. Right-click anywhere in the Sample/Test Summary and choose Paste Multiple from the context menu.

   The Paste Multiple dialog box is displayed.
7. Type the number of orders that you want to create, and the order ID to start from.
8. Click OK.

   A status dialog box shows how many orders are completed and how many remain.

Tips

- Step 4: You can also choose Edit > Copy.
- Step 6: You can also choose Edit > Paste Multiple.
- The order IDs that are created will be consecutive.
- The new order IDs must not conflict with any existing order ID, otherwise, the order request will fail.

Requesting a dilution

If a test result is out of range or a sample needs diluting before a test is run on it, you can request a test with one of the following types of dilution factor.

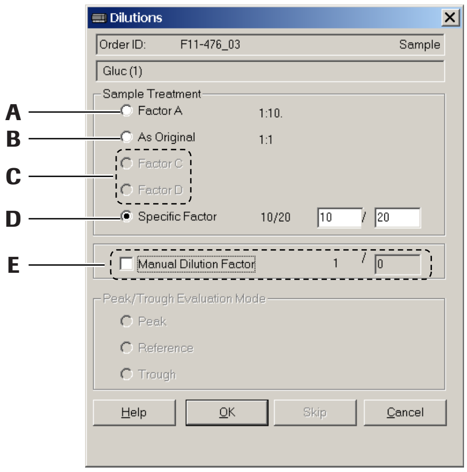
Dilution factor	Description
Factor	Select a predefined dilution or concentration factor. The system performs the dilution or concentration according to the factor you choose.
As Original	Use the original dilution.
Specific Factor	Select this option and type a dilution factor. The system performs the dilution according to the factor you specify.
Manual Dilution Factor	Select this option if you want to dilute the sample yourself. Type the dilution factor you are going to use. When you have performed the dilution, replace the sample tube (which now contains the diluted sample) in its original position on the same rack. All subsequent tests are performed on the diluted sample.

► To request a test with a dilution factor

1. Click Orders on the navigation bar.
2. Click the Sample tab
3. In the Sample/Test Summary group, right-click the test and choose Dilutions from the context menu.

   The Dilutions dialog box is displayed.
4. Select the required option button for a predefined dilution factor, a specific factor, or a manual dilution.
5. Specify the dilution factor, if required.
6. Click OK.
7. Click Save in Sample tab (when you have specified all the tests for the current

order).



Order ID: F11-476_03 Sample

Gluc (1)

○ Factor A 1:10.

○ As Original 1:1

○ Factor C

○ Factor D

● Specific Factor 10/20 10 / 20

☐ Manual Dilution Factor 1 / 0

○ Peak

○ Reference

○ Trough

A *Select a predefined dilution factor for an automatic dilution.*

B *Use the original sample dilution.*

C *These factors have not been defined for this test.*

D *Select to specify a dilution factor for this test and sample.*
Specify the values for an automatic dilution.

E *Select this box if your sample has been diluted manually. Type the dilution factor.*

Tips

- For an automatic dilution, the diluent and sample are mixed automatically in a cuvette.
- For a manual dilution, you mix the diluent and sample manually, then load the tube containing the diluted sample onto a rack.
- Do not use barcoded sample tubes for samples that require manual dilution. The barcode does not contain any information on the manual dilution factor.
- Roche recommends not to use manual dilution for ISE tests. The test range of all ISE tests (direct and indirect) covers all physiological ranges, and therefore, there is no need to measure electrolytes from off-line diluted samples.
- The sample is run using an automatic dilution factor if the result flag demands it. This depends on the configuration of your system, and overrides any dilution that you have requested.
- For some tests dilution by the system is not allowed. In these cases, Roche has set Automatic Dilutions to Disabled in Configuration / Test / Dilutions. You cannot change this setting. You can set Automatic Dilutions to Off in Configuration / Test / Dilutions, and then specify a Specific Factor.
- Define dilution factors for a test in Configuration / Tests / Dilutions.

Deleting tests

You can delete tests from an order, or you can delete the whole order.

► To delete a test

1 Click Orders on the navigation bar.

2 Click the Sample tab.

3 Type the order ID in the ID box and press Tab.

4 In the Sample/Test Summary group, right-click the test to be deleted and choose Delete from the context menu.

5 Click Save.

Tips

- If the order has not yet been saved, click Clear to remove all tests.
- You cannot delete finished tests with results that have not been accepted yet.

Purging and deleting orders

You can purge orders manually at any time, or delete them automatically at BOD. The main reason for purging orders is to free the order IDs for re-use.

Purging orders removes the order ID from the Orders work area. This means that you can reuse the IDs after purging orders. In the Results work area, the order ID is still visible; the results are not removed. Each order ID is associated with a date and time so that you can always refer to a specific order by its ID, its date, and its time stamp. This ensures that each order is unique.

Preconditions You can only purge an order when:

- The system is in Standby or Sleeping state.
- There are no pending tests belonging to this order.
- The associated results have been accepted.
- The associated results have been transmitted to the host, if applicable.
- The associated samples have been removed from the system.

► To purge orders manually

1 Choose Tools > Purge Orders.

2 Click Yes on the Confirm Purge Orders dialog box.

► To delete orders automatically at BOD

1 Click Configuration on the navigation bar.

2 Double-click Database in the System group.

3 Click the Automatic Actions tab.

4 In the Delete Orders After box, type the number of days after which the order should be deleted.

5 Click OK.

Tips

- Type 0 (zero) to delete at the next Begin of Day all of today's orders, that is all orders defined between the time of the last and the next Begin of Day time.
- Type 1 to delete at Begin of Day all orders that were created more than 24 hours before Begin of Day time.

► To delete a single order

1 Click Orders on the navigation bar.

2 Click the Sample tab.

3. Type the order ID in the ID box and press Tab.
4. Right-click anywhere in the Sample tab and choose Delete Order from the context menu.

   The system prompts you to confirm the deletion.
5. Click OK.

Tips

- You cannot delete an order if the sample is on board.
- Step 4: You can also choose Edit > Delete.

Results

Reviewing and validating results

This chapter describes the Results work area and how to use it. It shows you how to review results for samples, calibrations, and controls. You can also validate results and rerun tests.

You find more information on result handling in Chapter 10, “Calibration” and Chapter 11, “Quality controls”.

In this chapter

Chapter **9**

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About results

Result handling and the way that information is displayed in the Results work area is determined in the system configuration. The sections below give examples:

Result handling

You can specify what happens to flagged and unflagged results. The possible automatic actions following a flag are None, Accept, Stop Test, or Rerun; the options available depend on whether the result was for a sample, calibration, control, or calculated result.

Note: When an automatic rerun is performed, the dilution is the same as that used for the last request.

Typically, the system is set up to automatically accept unflagged results. They are then displayed in the Sample, Calibration, and Quality Control tabs in the Results work area. Flagged results are usually displayed in the Validate tab in the Results work area so that you can review them, and either accept them manually, or rerun them.

👁 *"Flags and recommended actions" on page C-6*

Raw data

You can specify how long raw data are kept in the database in Configuration / Database / Automatic Actions. You can look at raw data values and a graph of the raw data over time in the Results work area.

👁 *"To review rate information for a result" on page B-126*

Lab. units

If you want to use units that are different from the predefined standard units, you can specify laboratory units as part of the test definition (Configuration / Tests / Laboratory). Enter an appropriate conversion factor.

Comparing results between instruments

If you want to compare results from the *Cedex Bio HT* analyzer with results from another instrument or methodology, you can specify a factor and an offset value (in Configuration / Tests / Laboratory) to accommodate operational differences between the two instruments or methodologies. The system applies the factor and offset to the results before displaying them in the Results work area.

Calculated Results

A calculated result is a mathematical relationship involving one or more test results, and optional numerical constants. You can define calculated results for tests (in Configuration / Calculated Results), and specify how to handle calculated result flags (in Configuration / Result Handling / Calculated Results). The system automatically calculates a calculated result if all the tests specified in the calculated result are requested in an order.

Note: When tests are requested in duplicate, the calculated result is only calculated for the first run of the test.

Reference ranges

You can define a general reference and a critical range for each test in Configuration / Tests / Evaluation. If the test result falls outside the defined range, the settings in Configuration / Result Handling determine what happens next.

Automatic dilutions

You can specify up to four automatic dilution factors for each test (in Configuration / Tests / Dilutions). The automatic dilution factors are used only when Automatic Dilutions is set to Sequential.

Purging results

Results are stored in a database on the hard disk. You can purge completed results to maintain disk space (Tools > Purge Results). If the instrument is connected to a host, the results are considered to be completed when they have been transmitted. Without host connection, the results are considered to be completed when they have been accepted.

“Purging results” on page D-67

Results at a glance

Use the following tables to locate specific tasks by work area and tab.

Work area	Tab	Tasks
Status	Missing & Blocked	• Review missing and blocked orders and requests that could not be run (no results).
	Samples	• Review samples on board. The color shows the status. double-click a rack position to display the details of the selected sample.
	Analyzer	• Review the number of pending or blocked tests and the number of results to validate.
Orders	All tabs	• No results are available in the Orders work area.
Results	Validate	• Review unaccepted results for orders, calibrations, and controls. • Accept sample, calibration and control results that have not been automatically accepted. • Rerun tests as original or with dilution. • Rerun calibrations and controls as original. • Monitor controls over time. • Review rate information for unaccepted sample, calibration, and control results. • Find specific orders and samples. • Display specific information by selecting filter options.
	Sample	• Review all results (whether accepted or not) listed by order date and order ID. • Find results of specific orders. • Display specific information by selecting filter options. • Review details for specific tests or orders.
	Calibration	• Review calibration curve parameters for a specific test. • Review calibration details in graphical form or as raw data.
	Quality Control	• Review QC results graphically by tests or controls. Use the From button to review only a selection of QC results. • Select the control mode (precision, accuracy, or limit). • Review statistics for each control mode. • Review details for QC results (including lot numbers). • Display specific information by selecting filter options.

Use the following table to locate specific tasks in the Configuration work area:

Icon	Tab	Tasks
Tests	Laboratory	- Specify correlation factor and offset for each test. - Specify for each test lab units, and a conversion factor if necessary.
	Evaluation	- Specify the result evaluation mode for each test (reference ranges, cut-off limits).
Database	Automatic Actions	- Specify the period after which result raw data is automatically deleted.
Result Handling	All tabs	- Turn result handling on or off.
	Calibration	- Specify actions for flagged and non-flagged calibrations for each test class.
	Quality Control	- Specify actions for flagged and non-flagged control results for each test class.
	Sample	- Specify actions for flagged and non-flagged sample test results for each test class.
	Calculated Results	- Specify actions for flagged and non-flagged calculated results.

Results work area overview

To access the Results work area, click Results on the navigation bar.

The Results work area has the following tabs:

Tab	Function
Validate	This tab lists orders, calibrations and controls that either require validation, are blocked, or are not on board. You can accept a result or rerun it. You can request a dilution for tests that you decide to rerun.
Sample	This tab lists all results of all orders.
Calibration	Use this tab to review the calibration results and the calibration history of a test.
Quality Control	Use this tab to review the quality control history of a test. Results for the quality controls are displayed graphically, allowing you to quickly locate those that are out of range.

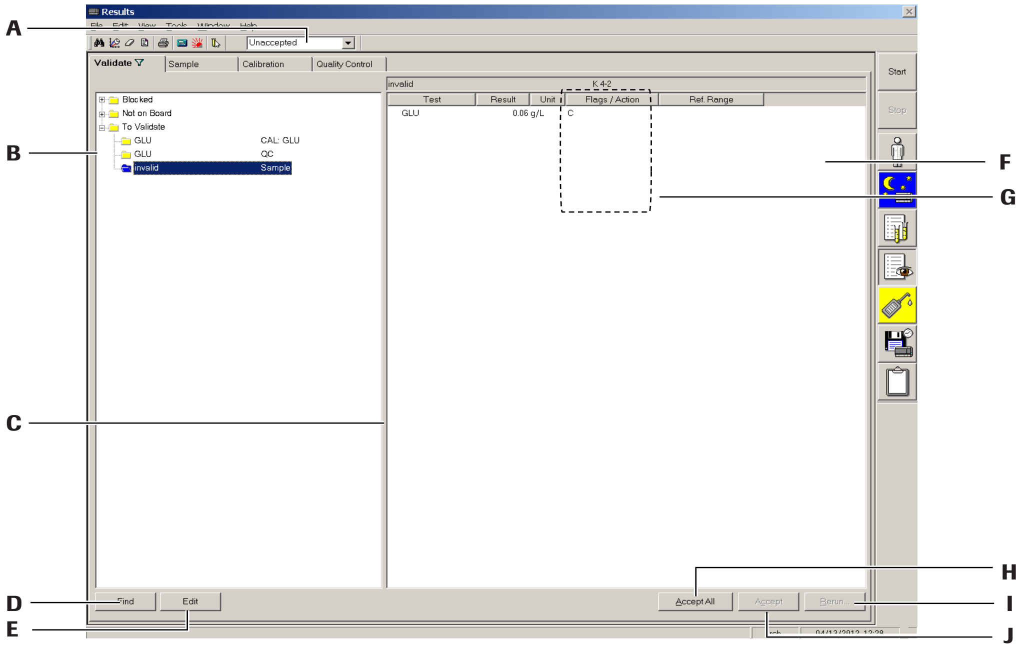
Context menu

You can right-click a sample, order, calibration, control or result in any tab to display the context menu. It contains one or more of the following frequently used commands:

Context menu item	Function
Accept	Accepts the selected result.
Accept All	Accepts all the results in the list.
Delete	Deletes the selected item.
Detail	Displays detailed information for the selected item.
Demographics	Displays demographics for the selected order.
Edit	Displays the appropriate tab on the Orders work area.
Exclude from statistics	Excludes the selected control result from statistics. The result is grayed out in the Quality Control tab.
List by	Switches between the available column headings to determine how the list is sorted.
Print Preview	Displays the report on-screen for you to review or print.
Rerun	Reruns the selected item.
Retransmit	Sends the results to the host again.
Statistics	Displays statistical information for the selected result.
Test Status	Displays information on the status of the test for the selected calibration or control.

Validate tab

The Validate tab lists all results that have not been automatically accepted. You can accept the result or rerun it. Use the flag information to help you to make the decision.


A
B
C
D
E
F
G
H
I
J
Results
Unaccepted
Validate
Sample
Calibration
Quality Control
Blocked
Not on Board
To Validate
GLU CAL: GLU
GLU QC
invalid Sample
invalid
K 4-2
Test
Result
Unit
Flags / Action
Ref. Range
GLU 0.06 g/L C
Start
Stop
Find
Edit
Accept All
Accept
Rerun...

A *From the list, select whether you want to display all results (All) or only the unaccepted results (Unaccepted)*

B *The Validate list shows orders, calibrations and controls whose results have not been accepted, are blocked, or are not on board. STAT orders are listed in bold type.*

C *To resize the columns, position your cursor here and click and drag the divider to the left or right.*

D *Use Find to display the results of a particular order*

E *Use Edit to modify a selected order. You are transferred to the appropriate tab in the Orders work area.*

F *The Results list shows results for the selected order, calibration, or control.*
A paper clip at the beginning of the line indicates a comment in the detail dialog box.
An asterisk at the beginning of the line indicates an accepted test. You only see asterisks in the Validate tab if the option in the list on the toolbar is set to display all results rather than only the unaccepted ones.

G *Flags are shown for each result. (Only the flags with the highest priority are displayed. Double-click the result line to display detailed information on all flags.)*
The results line is grayed out and the Flags/Action column shows Reactivated if a rerun has been requested.

H *Accept all results currently displayed in the Results list.*

I *Rerun the selected test with dilutions. The Dilutions dialog box is displayed.*

J *Accept the selected result(s),*

Tips

- The Validate tab can contain the following folders and information:

Folder	Contents
Blocked	Orders with at least one test with the Blocked status.
Not On Board	Orders for which there are tests to be performed, and for which the sample is not on board the system.
To Validate	Orders with results that need validating.

- Only folders that contain entries are displayed in the Validate list.
- To follow the logical job sequence, work through the entries in the list from top to bottom.
- Click a sample, calibration, or control order in the Validate list to display the corresponding results on the right side of the tab.
- Double-click any item in either of the lists to display more details for that item.
- Right-click an order and choose Demographics > Order to display the order demographics for the selected order.
- The reference range for the test is shown by the parentheses (---). The asterisk * shows the position of the result compared with the reference range:

Graphic	Meaning
*--(---)---	Result less than the reference range.
<--(---)---	Result much less than reference range.
---(-*-)---	Result inside the reference range.
---(---)-->	Result much greater than reference range.
---(---)-*-	Result greater than the reference range.

- Press F1 to display Help for this tab.
- To display Help on a blocked test, select the test on the Results - Detail dialog box, and press F1.

Factors affecting the information you see here

The information displayed depends on how your system has been set up:

- The settings in Configuration / Results Handling determine which results are automatically accepted and which must be manually validated here. Typically, results without flags are accepted automatically; orders are listed only if they contain one or more flagged result.

  Accepted orders are displayed in the Sample tab.
- The units displayed depend on the lab units defined for your system in Configuration / Tests / Laboratory.
- There are two options in the filter list on the toolbar:

  Unaccepted: Only unaccepted results are displayed.

  All: All results are displayed. Results that have been accepted are marked with an asterisk.

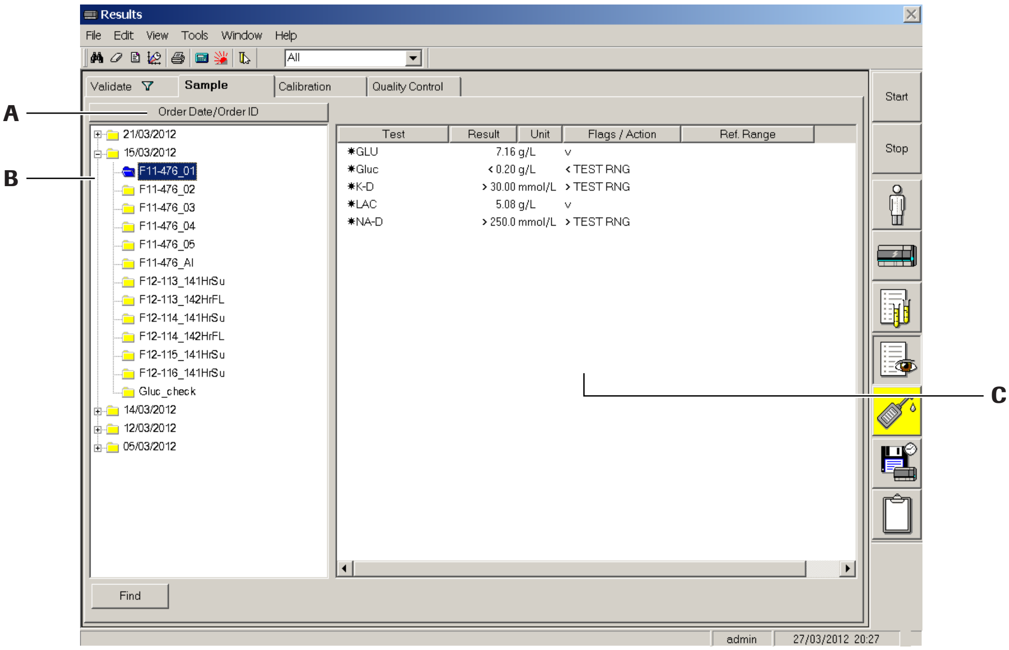
  If you choose Unaccepted, the filter icon ▼ is displayed on the tab label.

Sample tab

Use the Sample tab to review result information of all orders on the system. This includes accepted and unaccepted results.

The functions on this tab are similar to those on the Validate tab.

👁 *“Validate tab” on page B-117*


Results
File Edit View Tools Window Help
All
Validate
Sample
Calibration
Quality Control
Order Date/Order ID
Start
Stop
Find
admin
27/03/2012 20:27
A
B
C

21/03/2012
15/03/2012
F11-476_01
F11-476_02
F11-476_03
F11-476_04
F11-476_05
F11-476_AI
F12-113_141HrSu
F12-113_142HrFL
F12-114_141HrSu
F12-114_142HrFL
F12-115_141HrSu
F12-116_141HrSu
Gluc_check
14/03/2012
12/03/2012
05/03/2012

Test	Result	Unit	Flags / Action	Ref. Range
✱GLU	7.16	g/L	v	
✱Gluc	< 0.20	g/L	< TEST RNG	
✱K-D	> 30.00	mmol/L	> TEST RNG	
✱LAC	5.08	g/L	v	
✱NA-D	> 250.0	mmol/L	> TEST RNG	

A *Change the display in this column by clicking the column header.*

B *The Orders & Samples list contains orders with unaccepted and accepted results.*

C *The Results list contains all results for the selected order.*

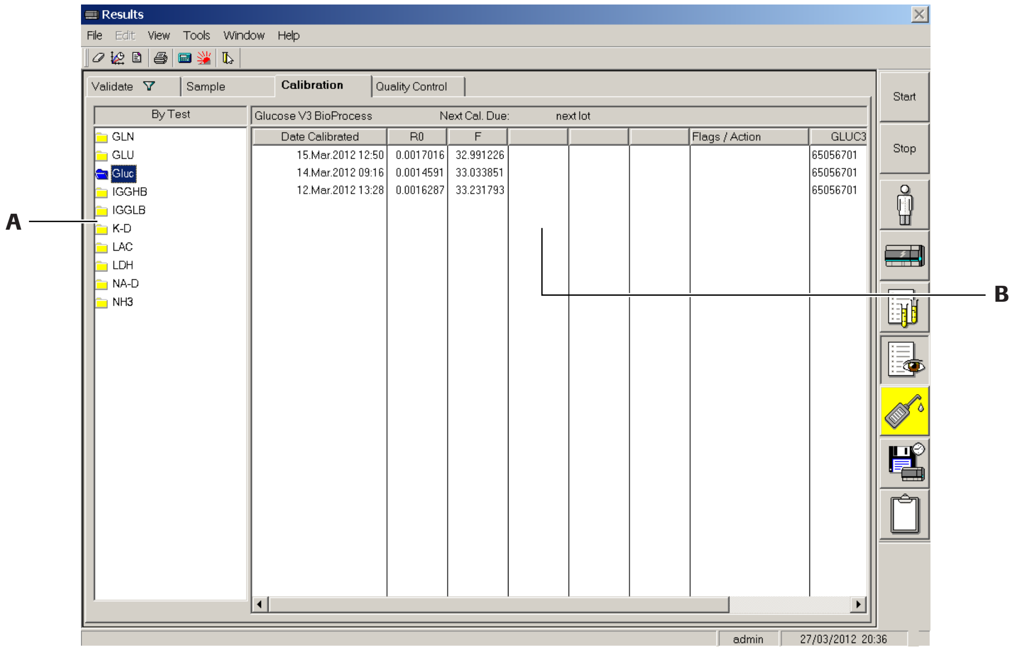
Tips

- The Samples & Orders list has a search facility; click anywhere in the list and type the first few characters of the item you are trying to find.
- Select All or the user defined filter in the filter list on the toolbar to define what information is displayed on the tab.
- Press F1 to display Help for this tab.

Calibration tab

Use the calibration tab to review the calibration history of each test. The functions on this tab are similar to those on the Validate tab.

"Validate tab" on page B-117



By Test

GLN
GLU
Gluc
IGGHB
IGGLB
K-D
LAC
LDH
NA-D
NH3

Glucose V3 BioProcess Next Cal. Due: next lot

Date Calibrated	R0	F				Flags / Action	GLUC3
15.Mar.2012 12:50	0.0017016	32.991226					65056701
14.Mar.2012 09:16	0.0014591	33.033851					65056701
12.Mar.2012 13:28	0.0016287	33.231793					65056701

A *The Test list shows all the tests on the system.*

B *The Results list shows the calibration history for the selected test.*
Scroll right to display flags and actions, and test and calibrator lot numbers.
If a dotted line is displayed in the Date Calibrated column instead of the date, the calibration is running or is not accepted.
If a dotted line is displayed across all the columns, a new calibrator lot has been used.

Tips

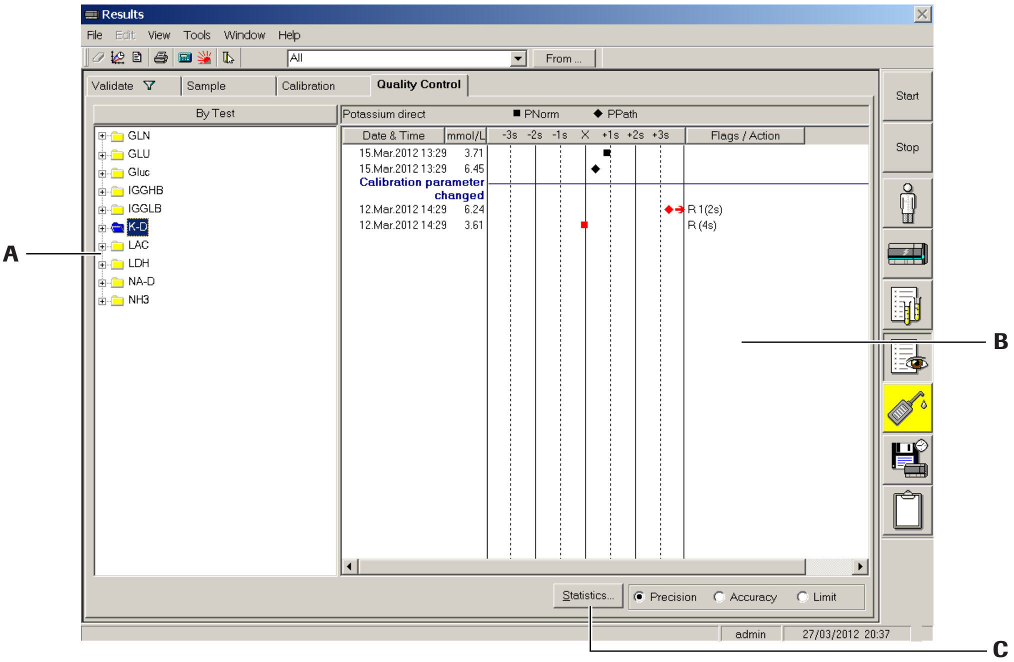
- The Test list has a mnemonic search facility; click anywhere in the Test list and type the first few characters of the test name to find a test.
- Press F1 to display Help for this tab.

"Validating calibration results" on page B-149
"Reviewing calibration history" on page B-151

Quality Control tab

Use the Quality Control tab to review the quality control history of a test. The functions on this tab are similar to those on the Validate tab.

"Validate tab" on page B-117
"Understanding control results" on page B-176


Results
File
Edit
View
Tools
Window
Help
All
From ...
Validate
Sample
Calibration
Quality Control
Start
Stop
By Test
GLN
GLU
Gluc
IGGHB
IGGLB
K-D
LAC
LDH
NA-D
NH3
Potassium direct
■ PNorm
◆ PPath
Date & Time
mmol/L
-3s
-2s
-1s
X
+1s
+2s
+3s
Flags / Action
Statistics...
● Precision
○ Accuracy
○ Limit
admin
27/03/2012 20:37
A
B
C

15.Mar.2012 13:29 3.71
15.Mar.2012 13:29 6.45
Calibration parameter changed
12.Mar.2012 14:29 6.24 R 1(2s)
12.Mar.2012 14:29 3.61 R (4s)

A *The Test list shows all the tests on the system and their associated controls.*

B *The Results list shows control results for the selected test.*
If a dotted line is displayed in the Date & Time column instead of the date, the control is running or is not accepted.
If a single control is selected and a dotted line is displayed across all columns, control lot values have been changed.

C *Use Statistics to display statistics for the selected test and its assigned controls. The statistics displayed depend on which control mode (Accuracy, Precision, or Limit) is selected. The Results QC Statistics dialog box shows the statistics for the selected test and control(s).*

Tips

- Results are removed from the Results work area if you use a new control lot.
- Click the column header at the top of the Test list to switch between By Test or By Control. The option you choose determines how the list is sorted.
- The Test list has a search facility; click anywhere in the Test list and type the first few characters of the test name to find a test.
- Up to three controls can be displayed for one test. Each control is displayed using a unique symbol (a square, diamond, circle etc.). Flagged results are displayed in red.
- To show results for one control only, select the control.
- Position your cursor over a column heading in the Date & Time row (for example, X or 1s) to view the assigned limit and the standard deviations.

- Position your cursor over a result to display the control name and the Westgard rule (if flagged) or the result (if not flagged).
- Right-click a result and choose Exclude from Statistics to exclude the selected result from the statistical analysis.
- Select All or the last user defined period in the filter list on the toolbar to define what information is displayed on the tab.

  To define a period, click From on the toolbar and use the View of QC Results dialog box to make the definitions.
- Press F1 to display Help for this tab.

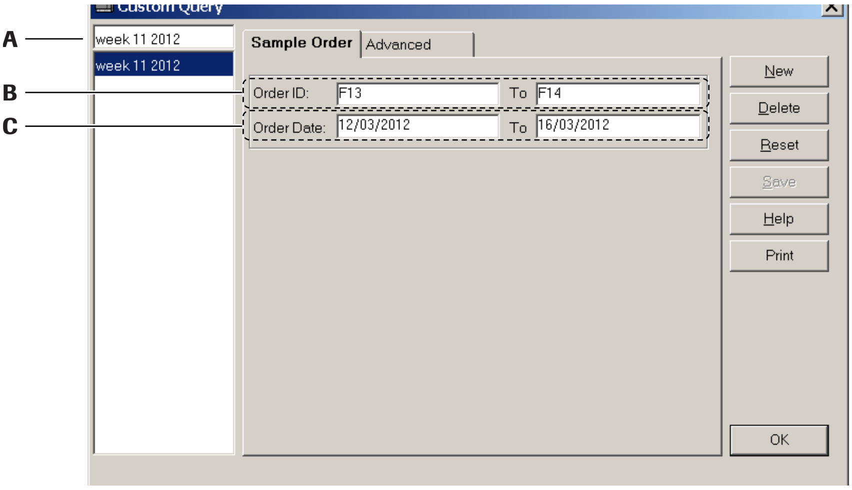
Selecting specific orders

Use the query function to filter orders displayed in the Sample result list according to the criteria you specify.

► To select specific orders using a query

1. Click Results on the navigation bar.
2. Click the Sample tab.
3. Choose View > Query > Custom.

   A blank Custom Query dialog box is displayed.
4. Click New to display the text boxes.
5. Type the information in the boxes as required.
6. Click Save.
7. Click OK to run the query.



week 11 2012
week 11 2012

Order ID: F13 To F14

Order Date: 12/03/2012 To 16/03/2012

A *Type the name of the query.*

B *Specify an order ID range. You can use the wildcards * and ?*

C *Specify a date range. The date format is dd.mm.yyyy.*

Tips

- Queries are valid only for the Sample tab in the Results work area.
- Where you can specify a range of values, you can specify none, a lower limit, an upper limit, or both a lower and an upper limit.
- You can use the wildcards ? (to represent a single character) and * (to represent one or more characters).
- If you do not want results to be filtered, select All in the filter list on the toolbar.
- You can run a previously defined query by selecting it in the filter list on the toolbar.

► To refine a query

1 Click Results on the navigation bar.

2 Click the Sample tab.

3 Choose View > Query > Custom.

A blank Custom Query dialog box is displayed.

4 Click New and complete the boxes as required.

5 Click the Advanced tab.

6 Specify the refinements that you wish to apply to the query by selecting the appropriate check boxes and options; for example, order status, order type.

7 Click Save.

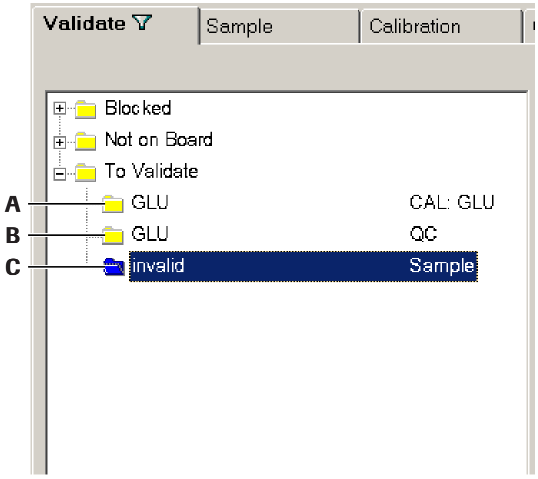
8 Click OK to run the query.

Displaying detailed information

You can double-click any item in the Results work area to get more detailed information. You can also access the same dialog boxes from the menu or by right-clicking the item.

► To display detailed information for orders

1. Click Results on the navigation bar.
2. Click the Validate, Sample, Calibration, or Quality Control tab.
3. Double-click an item in the list on the left side.

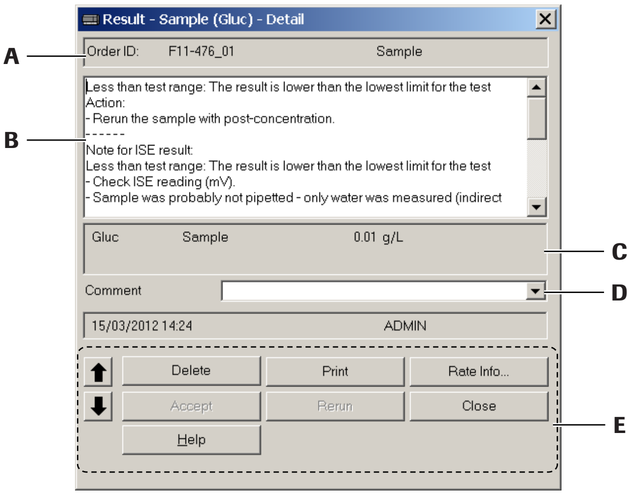


A *Calibrator*
B *Control*
C *Order*

► To display detailed information for individual results

1. Click Results on the navigation bar.
2. Click the Validate, Sample, Calibration, or Quality Control tab.
3. Select an item in the list on the left side.
4. Double-click a result line in the Results list (on the right side).

   The corresponding Results - Detail dialog box is displayed. The format of the dialog box is determined by the type of result that you are viewing. For example, when you double-click a sample, the Sample - (Test) - Detail dialog box is displayed:


Result - Sample (Gluc) - Detail

Order ID: F11-476_01 Sample

Less than test range: The result is lower than the lowest limit for the test
Action:
- Rerun the sample with post-concentration.

Note for ISE result:
Less than test range: The result is lower than the lowest limit for the test
- Check ISE reading (mV).
- Sample was probably not pipetted - only water was measured (indirect

Gluc Sample 0.01 g/L

Comment

15/03/2012 14:24 ADMIN

A *Sample and order details.*

B *Recommended user actions based on the flags generated.*

C *Test name, result value and unit, and reference value(s).*

D *You can type text into the Comment box, or select a predefined comment from the list.*

E *For details on the buttons, see below.*

Buttons

Button name	Function
Delete	Delete this result.
Print	Print a screen shot of this dialog box to the current default printer.
Rate Info	Display rate information for this result.
Accept	Accept the result.
Rerun	Rerun the test. For samples: The rerun result is recorded in addition to the existing result. You can then accept the rerun result. The Reactivated status is added to this entry. For calibrations: The old result is removed from the dialog box. For controls: The old result is frozen and displayed in grey. The Deleted status is added to this entry.
Close	Close this dialog box. Any comments you have added while the dialog box was open, are saved automatically.
Help	Display Help topic for this dialog box.
Up/Down Arrow	Use the arrow buttons to review details of other tests in the same order.

► To review rate information for a result

1 Click Results on the navigation bar.

2 Click any tab.

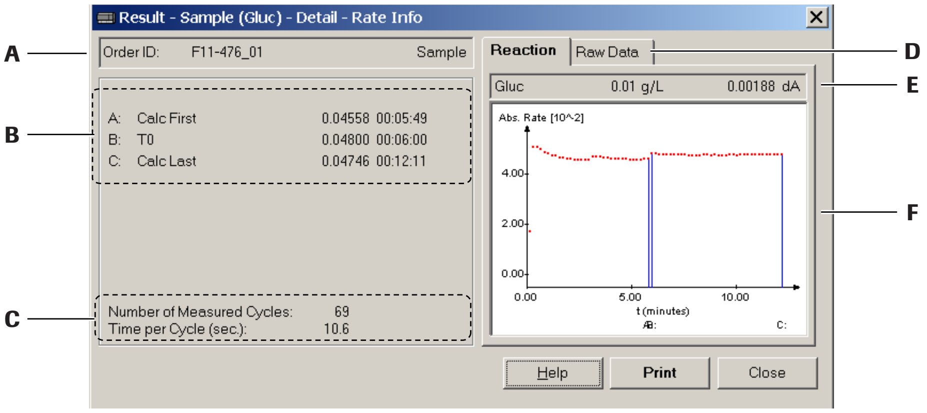
3 Select an item in the list to the left to display the results.

4 Double-click a result in the Results list.

The Results - Detail dialog box is displayed.

5 Click Rate Info.

The Rate Info dialog box is displayed. For example:



Result - Sample (Gluc) - Detail - Rate Info

Order ID: F11-476_01 Sample

A: Calc First 0.04558 00:05:49
B: T0 0.04800 00:06:00
C: Calc Last 0.04746 00:12:11

Number of Measured Cycles: 69
Time per Cycle (sec.): 10.6

Gluc 0.01 g/L 0.00188 dA

A *Order details.*

B *The calculation parameters differ depending on the type of test.*

C *The number of measured cycles and the time per cycle (10.6 sec).*

D *Click the Raw Data tab to review the numerical raw data.*

E *Result and rate of the test.*

F *Graph of the raw data over time.*

Tip

Raw data is automatically deleted after a number of days (defined in Configuration / Database / Automatic Actions).

Working with results

You can perform the following tasks on the Validate and Sample tabs of the Results work area:

- Accept results
- Rerun results
- Delete test results
- Archiving results

These tasks are described in the following sections.

Accepting result or rerunning tests

When one or more results in an order are flagged, all the results for that order are displayed in the Validate tab, provided you have chosen All in the filter list on the toolbar to display all results. You can accept all of the results, or you can accept some and rerun others. Note that results are flagged to indicate a problem, and you should not accept them without careful consideration.

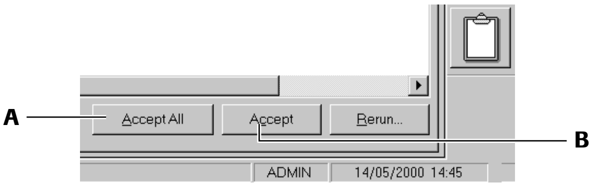
► To accept a result

1 Click Results on the navigation bar.

2 Click the Validate tab.

3 In the To Validate folder of the Validate list, select an order, calibration, or control.

4 Select a result and click Accept.



A *Accept all results which are listed for the selected item.*

B *Accept the selected (highlighted) results only.*

► To rerun a test

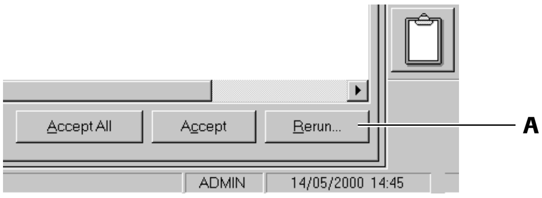
1 Click Results on the navigation bar.

2 Click the Validate tab.

3 In the Validate list, select an order, calibration, or control.

4 Select a result.

5 Click Rerun.



A *Rerun the selected test.*

Tips

- When you click Rerun, the Dilutions dialog box is displayed.

  "Requesting a dilution" on page B-107

- Rerunning a calibration automatically reruns the corresponding controls, and any sample tests for this test, provided the results of the control and tests were not accepted.

Monitoring processes

When the same test has been performed several times for the same batch, you can use the statistics facilities to compare the test results over time.

► To show statistics for results of a batch

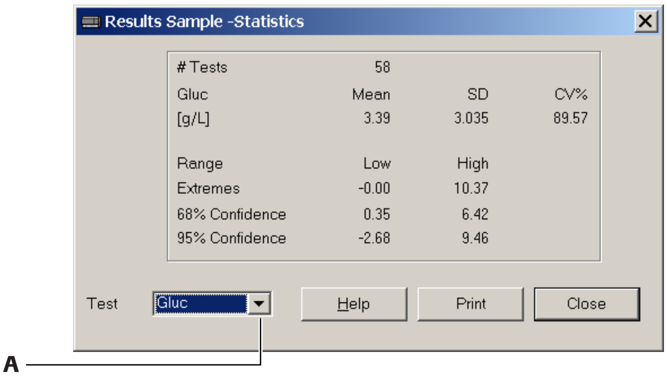
1 Click Results on the navigation bar.

2 Click the Sample tab.

3 Select an item in the Samples & Orders list. The corresponding results are displayed in the Results list.

4 Right-click a result in the Results list and choose Statistics.

The Results Sample - Statistics dialog box is displayed.



Results Sample -Statistics

# Tests	58		
Gluc	Mean	SD	CV%
[g/L]	3.39	3.035	89.57
Range	Low	High	
Extremes	-0.00	10.37	
68% Confidence	0.35	6.42	
95% Confidence	-2.68	9.46	

Test: Gluc

A *Select a different test from the list.*

Tip

If the test selected was a rerun, only the last measured results are included in the statistics.

Deleting information from the Results work area

In the Results work area, you can delete test results, orders, samples, and data generated on a particular date. If your system is not set up to perform an automatic purge at BOD, you can manually delete results so that you can re-use order numbers.

Purging results

The *Cedex Bio HT* analyzer is designed to store safely large quantities of results, typically for one year. As part of long-term data management, you should periodically delete results manually, at the very latest when the Database Full system message is displayed.

By default, results from sample tests, calibrations, and controls are kept indefinitely.

Purging removes completed results from the system. After purging, these results are no longer available on the system; you cannot retrieve them from the Results work area. When requesting statistics information, the statistics values are recalculated on the basis of the remaining test results.

Purging results manually can take considerable time. During this time, the system must remain in Standby; you should not attempt to insert a rack while a purge is in progress.

Preconditions for purging results

The system should be in the Standby or Sleeping state.

A sample test result is purged, provided that

- The associated sample is not on board.
- The result is accepted.
- The result has been transferred to the host, if you work with a host system.

The associated order ID is purged as well, provided that

- There are no pending test orders associated with this ID.

Tips

- Provided the above conditions are met, order IDs are deleted, even when tests were never performed for these orders, for example after inserting a rack with barcoded sample tubes and removing it again.

When purging results, the following information is deleted

- Results
- Calculated results that were derived from purgeable results
- Test orders
- Order IDs

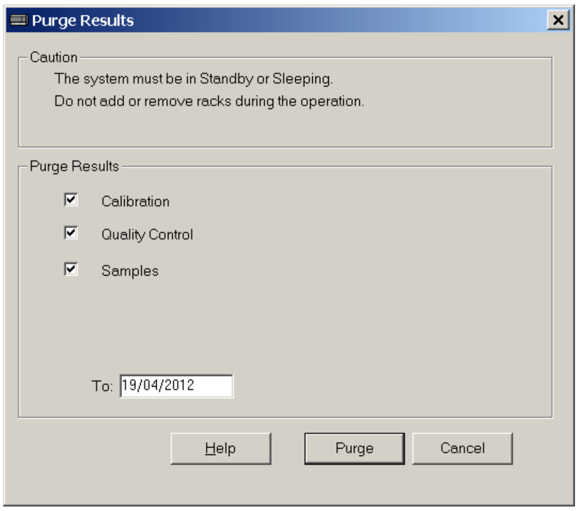
Tips

- Before you purge results, you should archive your current calibration, control, and sample results (File > Archive Results).

► To purge results

1 Choose Tools > Purge Results on any work area.

2 The Purge Results dialog box is displayed.



Purge Results

Caution
The system must be in Standby or Sleeping.
Do not add or remove racks during the operation.

Purge Results
☑ Calibration
☑ Quality Control
☑ Samples

To: 19/04/2012

3 Select or clear the Calibration, Quality Control, and Samples check box to choose the kind of test results you want do delete.

4 If you selected the Samples box, select the Purge all samples... box to delete in a further step all samples that will be without associated orders and results. The samples are deleted irrespective of the date specified on this dialog box.

5 In the To box, type the date up to which you want to delete the results. All results older than that date will be deleted.

6 Click Purge.

A status window is displayed while the results are being purged. The purging action may take quite some time, depending on the number of results that need to be deleted.

► To delete a single result

1 Click Results on the navigation bar.

2 On any of the tabs, right-click an item, and choose Delete from the context menu. The Confirm Delete dialog box is displayed. The text on this box tells you exactly what data will be deleted.

3 On the Confirm Delete dialog box, click Yes.

Tip

Depending on your user rights, this option may not be available to you.

Deleting orders

► To delete an order

For details on deleting orders, see “Purging and deleting orders” on page B-109.

1 Click Results on the navigation bar.

2 Click the Validate tab.

3 In the Validate list, right-click an order and choose Delete from the context menu.

The Confirm Delete dialog box is displayed. The text on this box tells you exactly what data will be deleted.

4 On the Confirm Delete dialog box, click Yes to delete the order, or No to cancel the deletion request.

Tips

- You cannot delete an order if a test belonging to that order is running, or if the sample is on board.
- You can delete orders in the Sample tab in the Results work area.

► To delete all orders for a specific date

1 Click Results on the navigation bar.

2 Click the Sample tab.

3 Right-click the required date and choose Delete from the context menu.

The Confirm Delete dialog box is displayed.

4 On the Confirm Delete dialog box, click Yes to delete all the orders or No to cancel the deletion request.

Deleting an empty orders folder

► To delete an empty folder

1 Click Results on the navigation bar.

2 Click the Sample tab.

3 Right-click the folder in the Samples & Orders list, and choose Delete from the context menu.

The Confirm Delete dialog box is displayed.

4 On the Confirm Delete dialog box, click Yes to delete the order or No to cancel the deletion request.

5 Type 0 (zero) in the Delete Orders after box in Configuration / Database / Automatic Actions.

Archiving results

You can save results on the system for future reference. You cannot reload archived results onto the system; you can only review them.

► To archive results

1 Click Results on the navigation bar.

2 Choose File > Archive.

The Archive Results dialog box is displayed.

3 Select the type of results to archive and - optionally - a date range.

4 Click Archive.

The Archive Result (File) dialog box is displayed.

5 Select the F disk drive, and specify a folder, file type, and file name for the archive.

6 Click OK.

Note

This is not a backup facility.

Reviewing archived results

You can use the review facility to browse the archived results.

► To review archived results

1. Click Results on the navigation bar.
2. Choose File > Review.

   The Review (File) dialog box is displayed.
3. Select the folder, file type, and filename from where the results should be read.
4. Click OK.

   The Review Results dialog box is displayed.
5. Use Find to locate a specific test.
6. Click Close.

Calibration

Working with calibrators and calibration results

This chapter tells you how to load, set up, request, and analyze results for calibrators.

In this chapter *Chapter* **10**

About calibration B-136
    Calibrators, calibration points, and curve parameters B-136
Calibrations at a glance B-138
Reviewing the status of calibrators on board B-139
    Displaying the remaining calibration interval for tests B-139
    Viewing rack positions for calibrators B-140
    Viewing missing calibrators B-141
Loading calibrators on board B-142
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Validating calibration results B-148
    Reviewing calibrations for validation B-148
    Reviewing calibration history B-150
Setting up calibrators B-153
    Specifying values for a new calibrator lot B-153
    Specifying a calibration interval B-155
    Loading and deleting calibrator definitions B-157

About calibration

Calibration is the process that establishes a relationship between (one or more) measured rates and the corresponding concentration of the calibrator. The measured rates are derived from instrument measurements, for example absorbance values.

When calibrations are performed

Calibrations are performed at regular intervals (defined in Configuration / Tests / General) to compensate for changes over time in reagents and in the measurement systems. Calibrations also have to be performed when certain physical events occur. These include:

- A change in cassette (reagent) lot.
- A change in a defined interval.

Validating calibrations

Each new calibration has to be validated either automatically or manually. No further calibration can be performed until the previous calibration has been validated and the results have been accepted. If flags are generated, you must determine their cause, and decide whether to accept or rerun the calibration. If a calibration for a particular test is not valid, all the results obtained with that test should be checked.

Lot numbers

The exact compositions of calibrators and reagents vary between lots. Therefore, it is important to check the lot numbers each time you replace a cassette or a calibrator. If you do not update the lot numbers and values recorded on the instrument, erroneous results can occur.

Calibration modes and calculations

Each calibration is assigned to a calibration mode by the manufacturer. Each mode represents a type of calibration curve and calibration curve parameter. From the calibration measurements, the system calculates the values of the appropriate parameters (called curve parameters) based on the calibration mode.

Calibrators, calibration points, and curve parameters

Linear calibrations

Tests for most enzymes and substrates have linear calibration curves, which require only a two-point calibration.

For a linear calibration:

- A two-point calibration is used; one calibrator has a known amount of analyte, the other is water, which is the zero calibrator.
- There are two curve parameters to be determined, known as F and R_0.
- The calibrators are placed next to each other on a sample rack. The calibrator with the highest concentration must be placed first (lower numerical position) on the rack.

Non-linear calibrations

Tests for some most specific proteins have non-linear calibrations.

For a non-linear calibration:

- Between four and six calibration points are used, depending on the calibration mode.
- There are four (K_C, R_0, A, B) or five (K_C, R_0, A, B, C) curve parameters, depending on the calibration mode.
- The calibrator is supplied as either a set of bottles or a single bottle from which the individual calibrators are made up automatically.

With a single calibrator and automatic dilution:

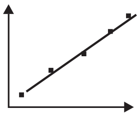
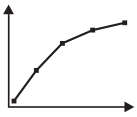
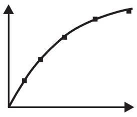
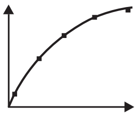
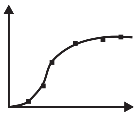
- There is only one calibrator to place on a rack.
- The system automatically makes up different dilutions of the calibrator to produce the required calibration points.

With a multi-calibrator set:

- Each calibrator has a different concentration of the analyte.
- The calibrators are placed in order on a rack with the calibrator with the highest concentration in the lowest numerical rack position.
- The software identifies individual calibrators as Std-1 (highest concentration), Std-2 (next highest concentration) and so on.
- All the calibrators in the set must be placed in adjacent slots on the same rack.

Calibration modes

Possible calibration modes are shown in the following table:

Calibration mode	**Attributes**
Linear regression 	Calibration curve: A straight line based on a calculated slope and offset. Number of calibration points: 0 - 6 Curve parameters: R_0, F • If no calibrators are used, both curve parameters, R_0 and F, are specified in the test definition file. • If one calibrator is used, one of the curve parameters, R_0 or F, is specified in the test definition file.
Linear interpolation 	Calibration curve: A straight line between adjacent points only. Number of calibration points: 3 - 6 Curve parameters: None
Logit/log 4 	Calibration curve: A curve characterized by the logit/log 4 formula, which has four calculated parameters. Number of calibration points: 4 - 6 Curve parameters: R_0, K_C, A, B
Logit/log 5 	Calibration curve: A curve characterized by the logit/log 5 formula, which has five calculated parameters. Number of calibration points: 5 - 6 Curve parameters: R_0, K_C, A, B, C
Spline 	Calibration curve: A curve characterized by a smooth polynomial function that is piecewise-defined. Minimum number of calibration points: 3 Curve parameters: None

Calibrations at a glance

Use the following table to locate specific tasks by work area and tab.

Work area	Tab	Tasks
Status	Missing & Blocked	• Review calibrators that cannot currently be used by the system, for example because they are not on board, expired, or some additional item such as a diluent is missing.
	Samples	• View calibrators on board; color shows the status. • Click a position to display the details for the selected calibrator.
	Test Status	• Review test with calibrator, intervals, rack position.
Orders	Calibration	• Review calibration. • Request a calibration. • Postpone a calibration. • Delete a calibration request. • Use Place Items or Sample Handling to manually assign calibrators to rack positions.
	Worklist	• Review the status of pending calibration requests during operation.
Results	Validate	• Review flagged calibrations. • Display the Calibration Definitions dialog and then Rate info. • Accept or rerun an unaccepted calibration. • Delete a calibration (if there are no dependent test results).
	Calibration	• Review calibrations by test. • Review curve parameters. • Review the calibration history. • Display the Details dialog to review data for individual calibrations, for replicates, and rate info. • Rerun or accept a calibration from the Details dialog.

Use the following table to locate specific tasks in the Configuration work area:

Icon	Tab	Tasks
Tests	General	• Specify calibrator, sample type, and interval for a calibration and whether replicates are to be run. Roche recommends to perform calibrations in duplicate.
Calibrators	Lot	• Specify a calibration lot number, expiry date, and the assigned values for a selected calibrator and test.

Reviewing the status of calibrators on board

You can check the status of the on-board calibrators, for example, to find out when they need replacing.

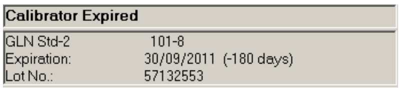
► **To view the calibrators on board**

1 Click Status on the navigation bar.

2 Click the Samples tab.

Samples, controls, and calibrators are displayed graphically. Cal indicates the presence of a calibrator.

3 Double-click a calibrator line to display details. For example:



Calibrator Expired

GLN Std-2 101-8
Expiration: 30/09/2011 (-180 days)
Lot No.: 57132553

What if?

The calibrator is expired	Replace the expired calibrator with one that is not expired. 👁 *“Specifying values for a new calibrator lot” on page B-154*
The calibrator is empty	Replace the calibrator. Make sure the lot number is the same as the previous calibrator. If the calibrator is from a new lot, you need to update the lot number first. 👁 *“Setting up calibrators” on page B-154* *“Calibrators, controls, and diluents” on page E-20*
The calibrator is blocked	One or more of the calibrators are not available, or the test cassette is empty. Replace the cassette(s) as required. 👁 *“Blocked orders, tests, calibrations, or controls” on page E-19*
The calibrator is not on board	Load the required calibrator. Make sure the lot number of the calibrator you load is the same as that specified in the calibrator detail.
The calibrator definitions are missing	The system has detected a calibrator, but the calibrator definition is missing or incomplete. 👁 *“Loading and deleting calibrator definitions” on page B-157*

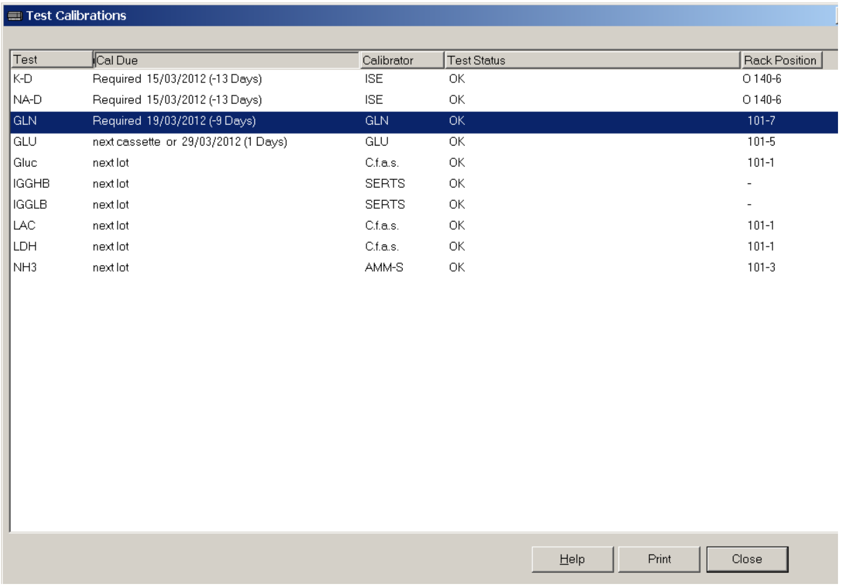
Displaying the remaining calibration interval for tests

Using the Test Calibrations function, you can display for all loaded tests, when the next calibration is due.

► **To check when a calibration is due**

1 Choose Tools > Test Calibrations on the menu bar.

The Test Calibrations dialog box is displayed.



Test	Cal Due	Calibrator	Test Status	Rack Position
K-D	Required 15/03/2012 (-13 Days)	ISE	OK	O 140-6
NA-D	Required 15/03/2012 (-13 Days)	ISE	OK	O 140-6
GLN	Required 19/03/2012 (-9 Days)	GLN	OK	101-7
GLU	next cassette or 29/03/2012 (1 Days)	GLU	OK	101-5
Gluc	next lot	C.f.a.s.	OK	101-1
IGGHB	next lot	SERTS	OK	-
IGGLB	next lot	SERTS	OK	-
LAC	next lot	C.f.a.s.	OK	101-1
LDH	next lot	C.f.a.s.	OK	101-1
NH3	next lot	AMM-S	OK	101-3

Tips

- This function is available from all work areas.
- You can click the Test Calibrations button on the toolbar instead of choosing Tools > Test Calibrations.
- Place all calibrators on the instrument before you generate and print the list. (The system updates the calibrator status of onboard calibrators only.)
- Click a column header to sort the list.
- Click Print to print a report with the contents of the Test Calibrations dialog box.

Viewing rack positions for calibrators

Typically, calibrators have a preassigned rack position on a sample rack. (Configuration / Lab /Reserve Positions) You can also specify an *ad hoc* location for a particular calibrator, for example, if you are calibrating a test that does not need calibrating very often. The system may also use barcodes to identify calibrators.

► To view preassigned rack positions for calibrators

If the rack is on board:

1 Click Status on the navigation bar.

2 Click the Sample tab.

3 Double-click the rack number

The calibration name for each position is displayed.

"Samples tab" on page B-70

If the rack is not on board:

1 Click Configuration on the navigation bar.

2 Double-click Lab in the System group.

3 Click the Reserve Positions tab.

"To load calibrators (without barcodes)" on page B-143

Tip

You can also click Place Items in the toolbar and then select the rack.

Viewing missing calibrators

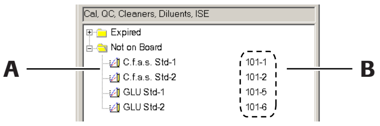
If a calibration is requested and one or more of the required calibrator(s) are not on board, the missing calibrators are listed in the Missing & Blocked tab in the Status work area.

► To view missing calibrators

1 Click Status on the navigation bar.

2 Click the Missing & Blocked tab.

3 Double-click the Not On Board folder in the Cals, QCs, Cleaners, Diluents, and ISE list:



C.f.a.s. Std-1	101-1
C.f.a.s. Std-2	101-2
GLU Std-1	101-5
GLU Std-2	101-6

A *Missing calibrators identified.*

B *Rack number and position.*

Tip

During operation, missing calibrators are also listed in the Blocked folder on the Worklist tab of the Orders work area.

Loading calibrators on board

There are two ways of loading calibrators, depending on whether the calibrator tube has a barcode or not.

► To load calibrators (with barcodes)

1. Prepare each calibrator according to the instructions on the package insert.
2. Remove the rack from its slot.
3. Transfer the calibrators to barcoded tubes on the rack.
4. Load the rack into an available slot.

Tips

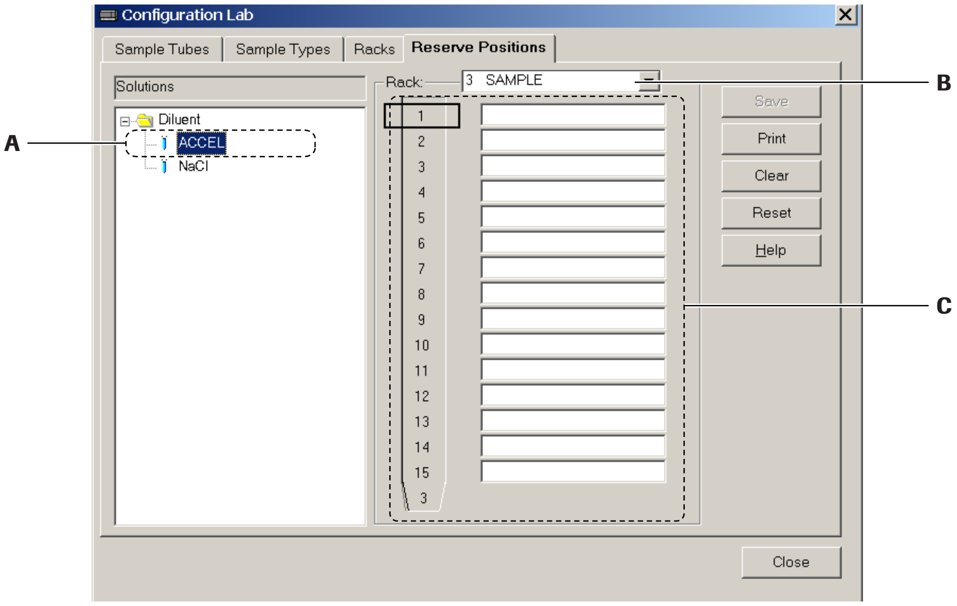
- When you load a multi-calibrator set:
  - All calibrators must have the same barcode.
  - Contact Roche for barcode specifications.
  - The calibrators must be placed consecutively on the rack, in descending concentration order.

    Start by placing the most concentrated solution in the available rack position with the lowest number.
- The barcode reader identifies each calibrator as the rack is loaded. You do not need to use either the Reserve Positions function or the Place Items dialog box (if you are using barcodes).
- Use slot I, if available, for calibrators. This slot is in the cassette area, which is cooled. Alternatively, you can use any available slot because the system identifies the rack and its contents as it is loaded.

► To load calibrators (without barcodes)

1. Prepare each calibrator according to the instructions on the package insert.
2. Remove a sample rack (preferably the sample rack in the cooled cassette area).
3. Click Configuration on the navigation bar.
4. Double-click the Lab icon.
5. Click the Reserve Positions tab.
6. Select the rack from the list (see B, below).
7. Click ⊞ on the Calibrator folder.

8 Drag and drop the calibrator(s) into position on the Rack graphic.


Configuration Lab
Sample Tubes
Sample Types
Racks
Reserve Positions
Solutions
Diluent
ACCEL
NaCl
Save
Print
Clear
Reset
Help
Close
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
3
A
B
C

Rack: 3 SAMPLE

A *Calibrator to place, requires one tube. The number in parentheses shows the number of tubes required on the rack for this calibrator or calibrator set.*

B *Click here to choose the rack number and name of rack type.*

C *The rack is represented as a graphic, and the tubes that have reserved positions on the rack are listed.*

9 Click Save.

10 Click Close.

11 Insert the sample rack.

Tips

- Step 8 - For a multi-calibrator set, the system automatically reserves the required number of positions, in the correct order. You cannot reserve positions for the calibrators if there are not enough positions (without gaps) available.
- Step 8 - The Move calibrators icon (that is displayed when you drag calibrators into position) shows the number of calibrators being moved.
- Click Clear to remove all the assignments from the rack.
- You can also use the Place Items dialog box to assign positions.

Requesting calibrations

Most calibrations are scheduled to run automatically, but you may need to request a calibration:

- If you start a new calibrator lot.
- If you change the test definition.
- If more than one cassette for the test are currently on board.
- If control measurements are outside the specified range.
- If all calibrations of the current lot are manually deleted.

Recommendations

- You should run any related control measurements after a calibration. If the calibration and control are not flagged, you can accept the calibration, provided this is not configured to be done automatically anyway.
- You should not accept a flagged calibration without further investigation.

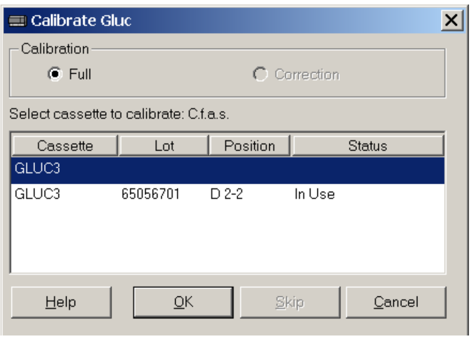
► To request a calibration

1 Click Orders on the navigation bar.

2 Click the Calibration tab.

3 In the Tests & Profiles group, click the buttons for the tests that you want to calibrate.

If more than one cassette for the test is currently on board, the Calibrate dialog box is displayed when you click a test button in the Calibration tab in the Orders work area.



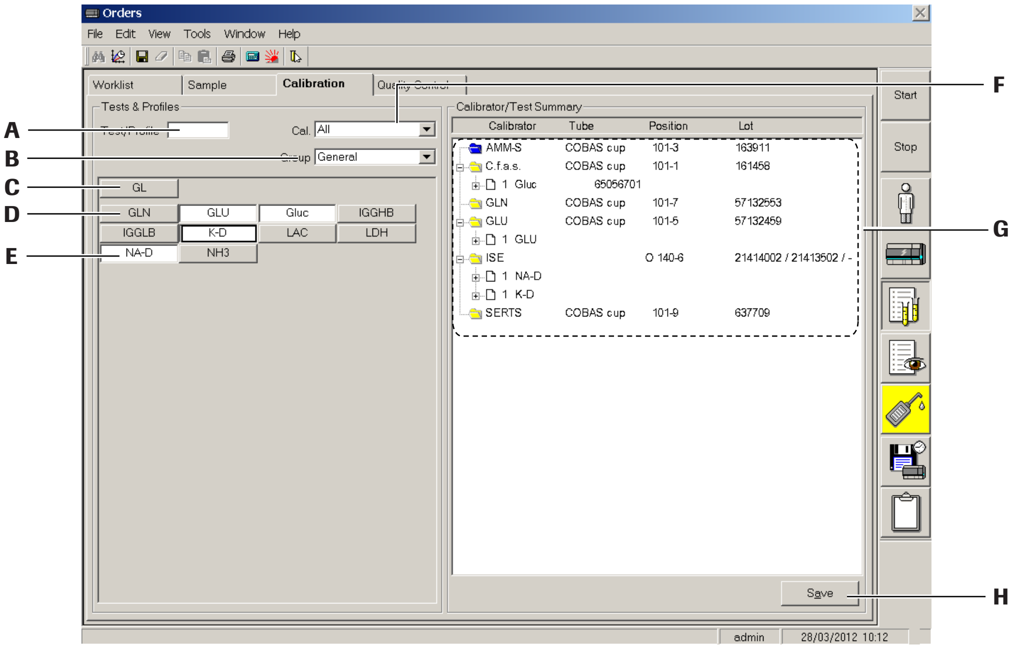
● Full ○ Correction

Select cassette to calibrate: C.f.a.s.

Cassette	Lot	Position	Status
GLUC3			
GLUC3	65056701	D 2-2	In Use

Select the cassette you wish to use.

4 Click Save.


Orders
File Edit View Tools Window Help
Worklist
Sample
Calibration
Quality Control
Tests & Profiles
Test/Profile
Cal.
All
Group
General
GL
GLN
GLU
Gluc
IGGHB
IGGLB
K-D
LAC
LDH
NA-D
NH3
Calibrator/Test Summary
Start
Stop
Save
admin
28/03/2012 10:12
A
B
C
D
E
F
G
H

Calibrator	Tube	Position	Lot
AMM-S	COBAS cup	101-3	163911
C.f.a.s.	COBAS cup	101-1	161458
1 Gluc	65056701		
GLN	COBAS cup	101-7	57132553
GLU	COBAS cup	101-5	57132459
1 GLU			
ISE		O 140-6	21414002 / 21413502 / -
1 NA-D			
1 K-D			
SERTS	COBAS cup	101-9	637709

A *You can select a test or profile for the calibration request by typing its name or number here.*

B *In the Configuration work area, tests can be assigned to groups. This feature can be used to reduce the number of tests displayed at one time in this tab. Select another group if you don't see the required test.*

C *Click profile buttons to request calibrations for all tests in the profile.*

D *Click test buttons to request a calibration for the test.*

E *Calibration already requested for this test.*

F *If you select a calibrator here, only the tests that are associated with the calibrator are displayed.*

G *The Calibrator/Test Summary lists all current requests for calibrations.*

H *Click Save to save the calibration request.*

Tips

- Only calibrators with current requests are displayed.
- A full calibration means that all the calibrators defined for the test (up to a maximum of six) must be run. The calibrators must be placed in consecutive positions on the same rack.
- When precalibrating a second cassette make sure that the corresponding controls are loaded on the instrument. If precalibration is performed without having the corresponding controls loaded on the instrument, subsequent QC will be performed using the first calibrated cassette.
- Manual requests do not reset the automatic intervals until the calibration is accepted.
- For an ISE Multi-test, selecting a calibration for any ISE test performs the calibration for all electrodes. No additional ISE tests are run until the calibration is accepted.
- You cannot delete calibrations that are running.

  "To delete a calibrator definition" on page B-159

- Press F1 to display Help for this tab.

Postponing a calibration

When the system requests a calibration, you can overrule this request by postponing the calibration.

You can postpone a calibration by moving the due date or event for the calibration. The period by which you can postpone a calibration depends on the way the calibration interval is defined for the test:

Due date or event	Postponement period
Interval	Interval
Each new cassette	Until the next new cassette
Each new lot	Until the next new lot

Caution

The Cedex Bio HT system is delivered with predefined calibration intervals for each test. The calibration intervals are carefully defined to guarantee reagent performance within the set on-board stability and shelf life of the reagents.
Roche does not recommend to change these default calibration intervals. Any change may alter the reagent performance and, as a result, may lead to erroneous results.

Preconditions

The following conditions must be met before you can postpone a calibration:

- A sample order exists for the test.
- An automatic calibration for the test is due now (the calibration interval has run out).
- When working with a host, an accepted and unflagged calibration must have been transmitted to the host.
- The test is blocked.

"Folders on the Missing & Blocked tab" on page B-68

► To postpone a calibration

1. Click the Calibration tab on the Orders work area.
2. In the Calibrator/Test Summary group, right-click the test that now requires a calibration and choose Postpone Calibration from the context menu.

   The calibration for the selected test is postponed by the period allowed for this test.

Tips

- In the Calibrator/Test Summary group, you can also choose Edit > Postpone Calibration instead of right-clicking the selection.
- You cannot postpone a calibration in advance. This function is only available while a test is due for calibration.
- You can postpone a calibration more than once.
- Sample and control results calculated with postponed calibrations are marked with “p”.
- Tests with postponed calibrations are listed in the BOD report.

- The fact that a calibration was postponed is recorded in the View Message dialog box (Messages > New Messages).
- If you select a calibrator in the Calibrator/Test Summary group instead of a test, the Postpone Calibration option is only available if the calibration can be postponed for all tests using this calibrator.

Validating calibration results

If any result in a calibration produces a flag, the whole calibration must be validated. Calibrations that run without creating flags are accepted automatically, provided the system is configured to do so (Configuration / Result Handling / Calibration).

If a calibration is flagged, you should not accept it without further investigation.

Reviewing calibrations for validation

Calibrations that require validation are displayed in the Validate tab in the Results work area. They are also listed in the Worklist of the Orders work area.

If a calibration is not accepted, any control or test results that depend on the calibration will be flagged and listed as well.

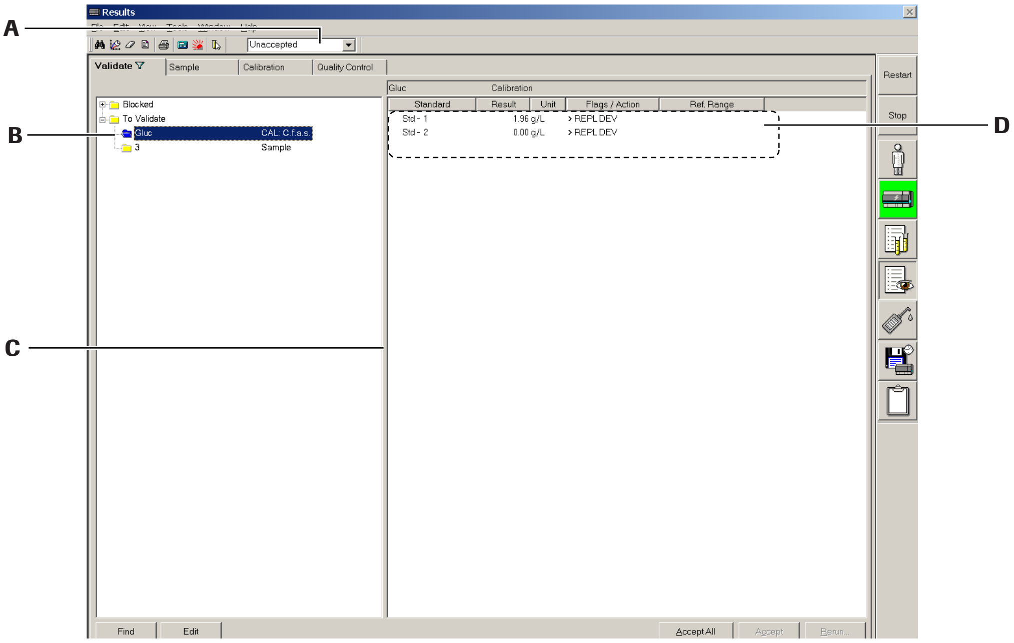
► To review calibrations for validation

1. Click Results on the navigation bar.
2. Click the Validate tab.
3. Select the required calibrator from the Validate list.
4. Resolve the action required from the flags generated.
5. Click the appropriate button:

   Accept: Has the same effect as Accept All.

   Accept All: Accept all the calibration results for the selected calibrator.

Rerun: Rerun the calibration. The current results are deleted. Any control or test that has not been accepted yet will be rerun automatically as well.


A
B
C
D
Results
Unaccepted
Validate
Sample
Calibration
Quality Control
Blocked
To Validate
Gluc
CAL: C.f.a.s.
3
Sample
Gluc
Calibration
Restart
Stop
Find
Edit
Accept All
Accept
Rerun...

Standard	Result	Unit	Flags / Action	Ref. Range
Std - 1	1.96 g/L		> REPL DEV	
Std - 2	0.00 g/L		> REPL DEV	

A *From the list, select whether you want to display all results (All) or only the unaccepted results (Unaccepted).*

B *The selected calibration.*

C *To resize the columns, position your cursor here and click and drag the divider. Move the divider to the right to reveal the sample type column.*

D *These calibration points are flagged. Double-click for more information.*
(A paper clip at the beginning of a line indicates that a comment has been entered in the Details dialog box.)

Tips

- To view additional details about the calibration, double-click a calibration line.

  "Reviewing calibration history" on page B-151

- Check to see if the flagged result occurs in more than one replicate.
- For a flagged calibration, select the calibration, then perform these steps:
  - Follow the recommended action for each flag.

    Chapter 12, "Result flags"

  - Check the assigned lot number of the calibrator against the actual lot number on the package insert. If these are different, rerun the calibration with the correct calibrator lot.
  - Check the curve parameters against those of existing accepted calibrations for the same test.
  - To check individual calibration points, double-click one of the calibration lines to open the Detail dialog.
- Press F1 to display Help for this tab.

Recommendations

- You should run the control measurements after a calibration. If the calibration and controls are not flagged, you can accept the calibration, provided this is not configured to be done automatically anyway.
- You should not accept a flagged calibration without further investigation.

Reviewing calibration history

The Calibration tab in the Results work area shows the calibration history of each test.

A calibration history lists the date and time, the curve parameters, and cassette lot numbers for the previous and current calibrations of a particular test.

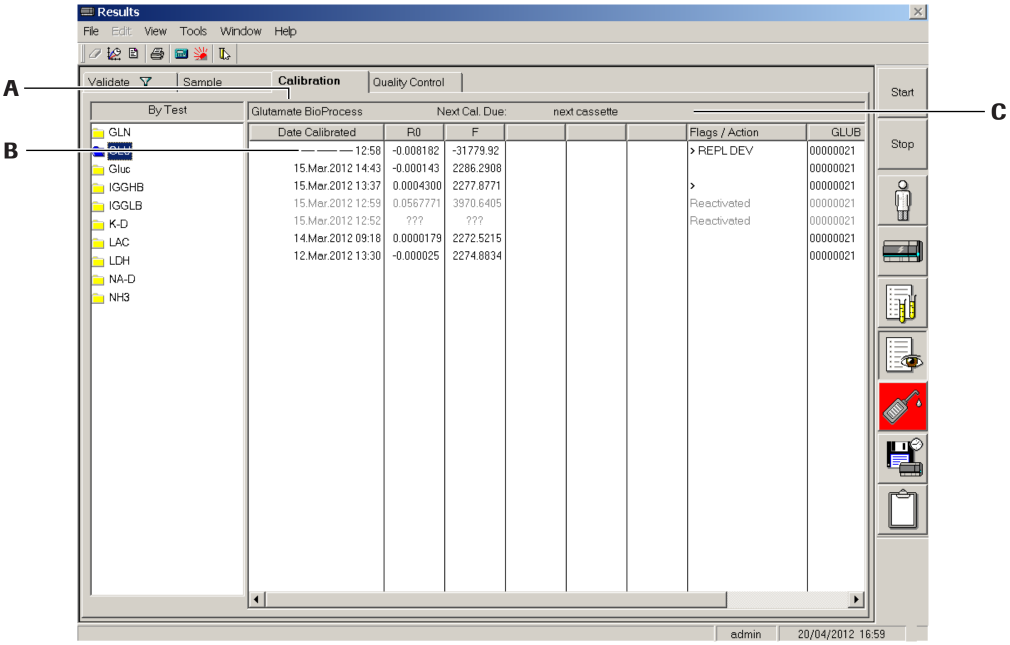
Use the calibration history to review trends (for example, to see if the instrument is running properly) or to examine a specific calibration in detail. You can display the calibration curve and raw data for each calibration, provided these results have not been deleted.

► To review the calibration history

1 Click Results on the navigation bar.

2 Click the Calibration tab.

3 Select a test from the By Test list.



Glutamate BioProcess Next Cal. Due: next cassette

Date Calibrated	R0	F				Flags / Action	GLUB
— — — — 12:58	-0.008182	-31779.92				> REPL DEV	00000021
15.Mar.2012 14:43	-0.000143	2286.2908					00000021
15.Mar.2012 13:37	0.0004300	2277.8771				>	00000021
15.Mar.2012 12:59	0.0567771	3970.6405				Reactivated	00000021
15.Mar.2012 12:52	???	???				Reactivated	00000021
14.Mar.2012 09:18	0.0000179	2272.5215					00000021
12.Mar.2012 13:30	-0.000025	2274.8834					00000021

A *Test name.*

B *This calibration is not accepted (dashed line instead of the date).*

C *Shows when the next calibration is due.*

Tips

- Double-click a calibrator line to display the Calibration Detail dialog box.
- Double-click a test in the By Test list to show the Test Status dialog box.

- A paper clip at the beginning of a calibration line indicates a comment in the detail dialog box.
- Scroll to the right to display lot numbers of the calibrator and reagent.
- A horizontal dotted line shows a lot change of a calibrator.
- Press F1 to display Help for this tab.

► To review calibration details

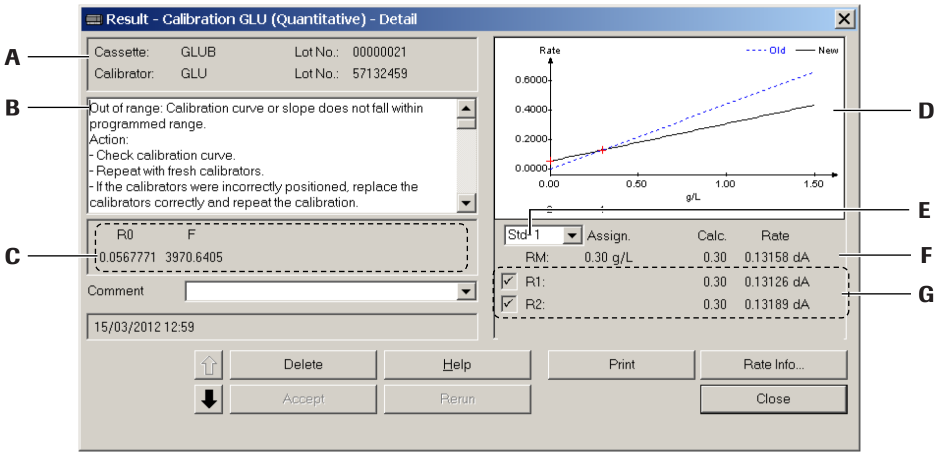
1 Click Results on the navigation bar.

2 Click the Calibration tab.

3 Select a test from the By Test list.

4 Double-click a calibration line.

The Calibration Detail dialog box is displayed.



Result - Calibration GLU (Quantitative) - Detail

Cassette: GLUB Lot No.: 00000021
Calibrator: GLU Lot No.: 57132459

Out of range: Calibration curve or slope does not fall within programmed range.
Action:
- Check calibration curve.
- Repeat with fresh calibrators.
- If the calibrators were incorrectly positioned, replace the calibrators correctly and repeat the calibration.

R0	F
0.0567771	3970.6405

Comment

15/03/2012 12:59

Std 1	Assign.	Calc.	Rate
RM:	0.30 g/L	0.30	0.13158 dA
☑ R1:		0.30	0.13126 dA
☑ R2:		0.30	0.13189 dA

A *The cassette and calibrator names and their respective lot numbers.*

B *Recommended user actions based on the flags generated.*

C *Calibration curve parameters according to the calibration mode.*

D *Graph of the calibration.*
Double-click the graph to expand it.
Drag the cursor along the line to see rate values for each point.

E *Calibrator (standard) for which values are listed.*

F *Mean values for the selected calibrator.*

G *Replicate values. Select the appropriate check box.*

Buttons

Button name	Function
Delete	Delete this calibration. The calibration results will be lost.
Print	Print details of this calibration.
Rate Info	Display rate information for this calibration.
Rerun	Rerun the calibration. The existing calibration results are deleted.
Accept	Accept this calibration. The values from this calibration will be used from now on to calculate results for this test.
Help	Display Help for this dialog box.
Close	Close this dialog box.
↑ ↓	Use the arrow buttons to display values for a previous or following calibrator.

► To review rate information for a calibration

1 Click Results on the navigation bar.

2 Click the Calibration tab.

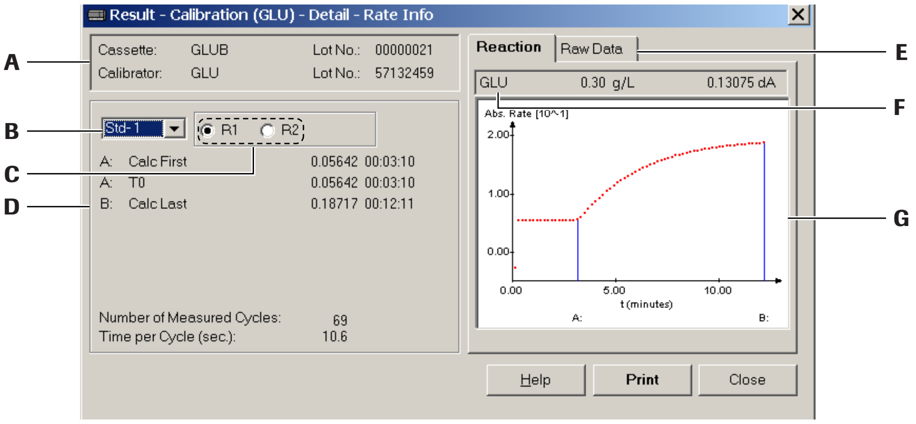
3 Select a test from the By Test list.

4 Double-click a calibrator line.

The Calibration Detail dialog box is displayed.

5 Click the Rate Info button.

The Result Detail Rate Info dialog box is displayed.



Cassette: GLUB Lot No.: 00000021
Calibrator: GLU Lot No.: 57132459

A: Calc First 0.05642 00:03:10
A: T0 0.05642 00:03:10
B: Calc Last 0.18717 00:12:11

Number of Measured Cycles: 69
Time per Cycle (sec.): 10.6

GLU 0.30 g/L 0.13075 dA

A *The cassette and calibrator names and their respective lot numbers.*

B *The calibration standard to which this data applies.*

C *Select a replicate.*

D *Measurement details. The parameters used and the calculation are test dependent.*

E *Click the Raw Data tab to review the numerical raw data vs. cycle number for this calibration.*

F *Test name.*

G *Kinetic of the reaction; graph of the raw data over time.*
Double-click the graph to expand it.
Drag the cursor along the line to see rate values for each point.

Setting up calibrators

Information about a calibrator for a test is stored in the test and calibrator definitions, which you can access through the Configuration work area.

Specifying values for a new calibrator lot

When you change calibrator lots you have to specify the lot number and expiration date, and the assigned values of the new lot.

The procedure to update calibrator lot numbers and values depends on whether you scan the barcode or enter it manually.

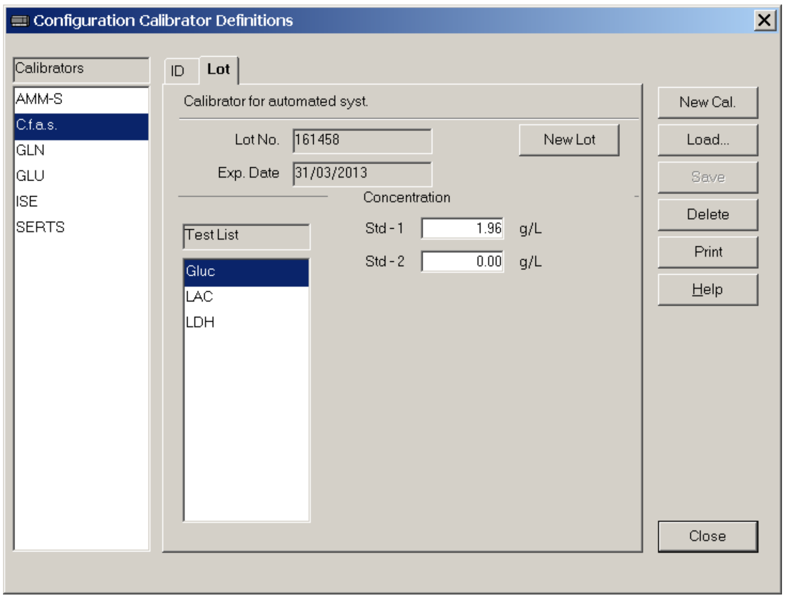
► To manually update a calibrator lot number

1 Click Configuration on the navigation bar.

2 Double-click Calibrators in the Definitions group.

3 Select the required calibrator from the Calibrators list.

4 Click the Lot tab.


Configuration Calibrator Definitions
Calibrators
AMM-S
C.f.a.s.
GLN
GLU
ISE
SERTS
ID
Lot
Test List
Gluc
LAC
LDH
Concentration
New Lot
New Cal.
Load...
Save
Delete
Print
Help
Close

Calibrator for automated syst.

Lot No. 161458

Exp. Date 31/03/2013

Std - 1 1.96 g/L

Std - 2 0.00 g/L

5 Click New Lot.

6 Type new values for the Lot No (Lot Number) and Exp. Date (Expiration Date), taking the values from the calibrator package insert.

7 Click Save.

8 Select a test from the Test List.

9 Type new values for each calibrator in the set (Std-1, Std-2, and so on), also taking these values from the calibrator package insert.

10 Click Save.

Tips

- The system must be in Standby or Sleeping mode.

- You must have the required user access level to perform this procedure.
- Results obtained using calibration curves on the basis of the previous lot values of this calibrator are not changed.
- Std-1 is the standard with the highest concentration.
- When updating the lot numbers for the ISE solutions, enter both the lot number and expiry date of the solutions. You can enter the lot definitions for all three solutions individually.

► To update a calibrator lot number using the barcode pen or handheld barcode scanner

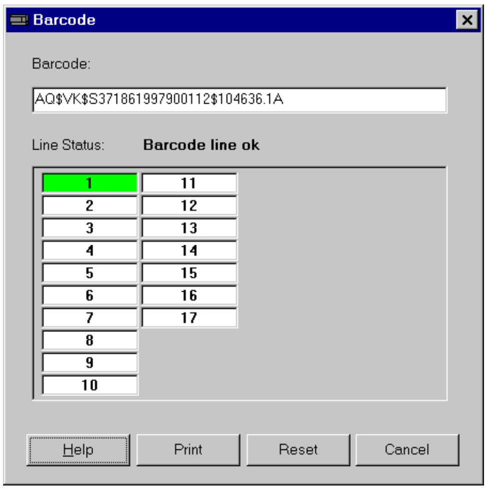
1 Click Configuration on the navigation bar.

2 Choose File > Barcode from the menu bar or click from the toolbar.

The Barcode dialog box is displayed.

3 Run the barcode pen over the first barcode line of the calibrator information sheet or read the barcode with the handheld barcode scanner.

After reading the first line of barcode, the information is displayed on the Barcode dialog box.



Barcode: AQ$VK$S371861997900112$104636.1A

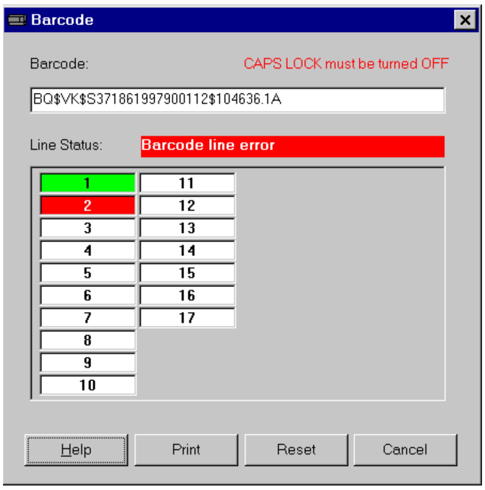
Line Status: **Barcode line ok**

The numbered boxes represent the barcode lines.

4 Read the rest of the barcode lines of the calibrator information sheet.

5 Watch the Barcode dialog box.

Correctly read lines are represented by green boxes, lines with reading errors by red boxes and a message on the Line Status box of the Barcode dialog box.



Barcode: CAPS LOCK must be turned OFF

BQ$VK$S371861997900112$104636.1A

Line Status: Barcode line error

- Using the barcode pen or handheld barcode scanner, re-read the barcode lines that are represented by a red box in the Line Status group of the Barcode dialog box.
- Click Reset to delete all lines and restart the whole reading process.

6 When all lines are read correctly (all boxes are green), the Barcode dialog box closes automatically, and a message is displayed, informing you of the successful conclusion of the reading process.

Tips

- To read and edit the read lot information, use Configuration / Calibrators / Lot or Configuration / Controls / Lot.
- Make sure Caps Lock on your keyboard is switched off.
- If you work with laboratory units other than the Roche standard units, the values read from the barcode sheet are automatically converted to your laboratory units, provided you specified the Lab Unit Factor (Configuration / Tests / Laboratory).

Specifying a calibration interval

The calibration intervals for each test are defined in the test definition. You can reduce and extend the calibration interval of a test.

Caution

The Cedex Bio HT system is delivered with predefined calibration intervals for each test. The calibration intervals are carefully defined to guarantee reagent performance within the set on-board stability and shelf life of the reagents.
Roche does not recommend to change these default calibration intervals. Any change may alter the reagent performance and, as a result, may lead to erroneous results.

► To specify a calibration interval

1 Click Configuration on the navigation bar.

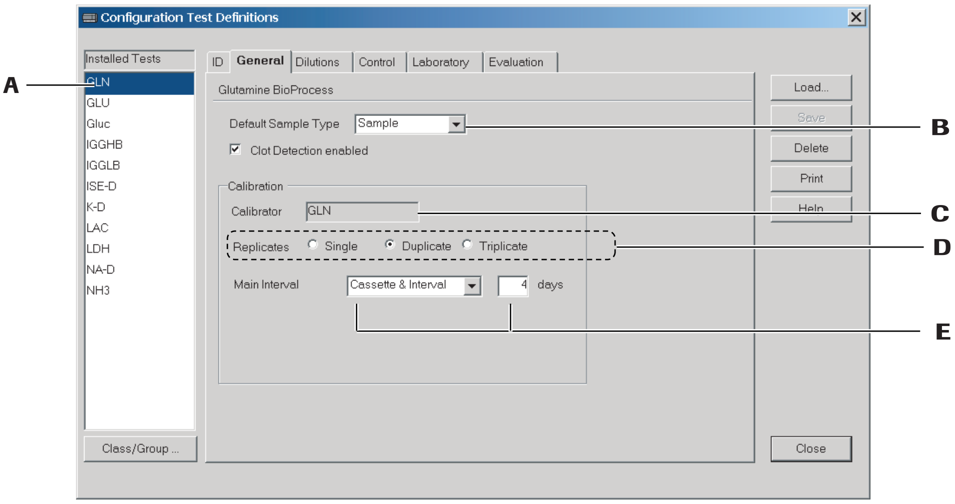
2 Double-click Tests in the Definitions group.

3 Click the General tab.

4 Select the required test from the Installed Tests list.

5 Complete the Calibration text boxes as required.

6 Click Save.


Configuration Test Definitions
Installed Tests
GLN
GLU
Gluc
IGGHB
IGGLB
ISE-D
K-D
LAC
LDH
NA-D
NH3
Class/Group ...
ID
General
Dilutions
Control
Laboratory
Evaluation
Load...
Save
Delete
Print
Help
Close
Calibration
A
B
C
D
E

Glutamine BioProcess

Default Sample Type: Sample

☑ Clot Detection enabled

Calibrator: GLN

Replicates ○ Single ● Duplicate ○ Triplicate

Main Interval: Cassette & Interval 4 days

A *Selected test.*

B *Sample type.*

C *Roche calibrator.*

D *If you select Duplicate or Triplicate, a mean value is calculated for each standard.*

E *Specify the interval type if necessary.*

Tips

- Change the Sample Type only if necessary.
- You can only use the predefined Roche calibrators. This parameter can not be changed.
- The system must be in Standby or Sleeping mode.
- You must have the required user access level to perform this procedure.
- You cannot modify a calibration interval if there is one or more unaccepted calibration curve for this calibrator or if there are unaccepted sample and QC results obtained on the basis of this calibrator.
- You cannot modify the calibration interval of ISE tests at all.
- The options for specifying a calibration interval are:

  None: No calibration interval.

  Interval: Calibration at time interval only.

  Cass-Lot & Interval: Calibrate at each new cassette lot or specified interval, whichever comes sooner.

  Cassette & Interval: Calibrate at each new cassette or specified interval, whichever comes sooner.

Loading and deleting calibrator definitions

If you get an update to a calibrator definition (for example, from a new Test Application Software (TAS)), use this procedure to load the new calibrator definition.

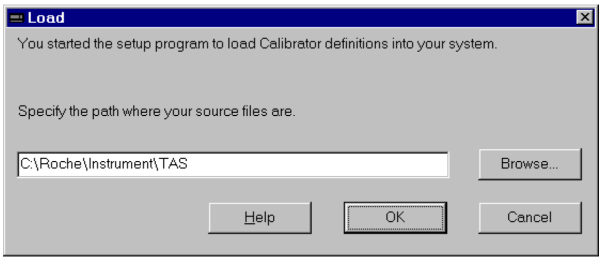
► To load a new calibrator definition

1 Click Configuration on the navigation bar.

2 Double-click Calibrators in the Definitions group.

3 Click Load.

The Load dialog box is displayed.



You started the setup program to load Calibrator definitions into your system.

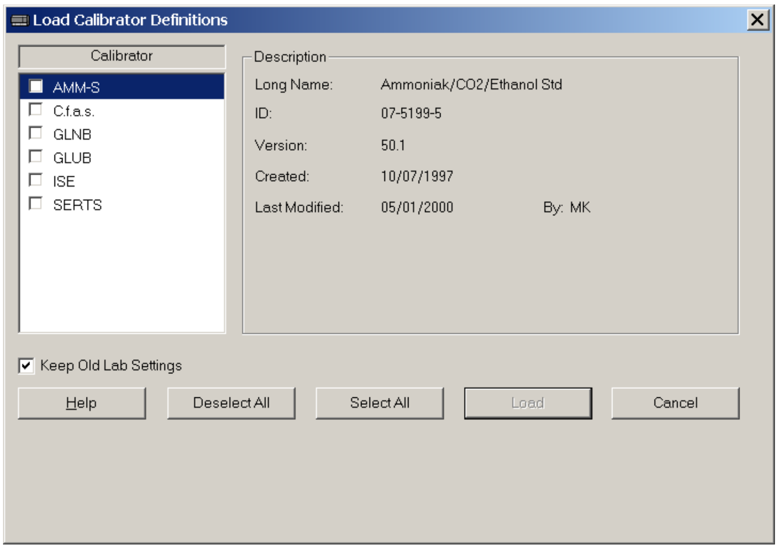
Specify the path where your source files are.

C:\Roche\Instrument\TAS

4 Click Browse and choose the drive and directory where the required calibrator definition is located. By default, the C:\Roche\Instrument\TAS path is selected. Alternatively, type the complete path.

5 Click OK.

The Load Calibrator Definitions dialog box is displayed.



☐ AMM-S
☐ C.f.a.s.
☐ GLNB
☐ GLUB
☐ ISE
☐ SERTS

Long Name: Ammoniak/CO2/Ethanol Std
ID: 07-5199-5
Version: 50.1
Created: 10/07/1997
Last Modified: 05/01/2000 By: MK

☑ Keep Old Lab Settings

6 Select the calibrators that you require.

7 Click Load.

A progress indicator is displayed.

8 When the calibrators have been loaded, click Cancel to close the Load Calibrator Definitions dialog box.

If you work with a barcode pen or handheld barcode scanner, perform step 11 and then read the barcode with the pen or scanner.

9 Select a calibrator from the Calibrator list

10 Click the Lot tab to review the lot information.

11 Click Save.

12 Click Close.

Tips

- You may be asked to update calibrator definitions from the Test Application Software (TAS) from time to time.
- Update the assigned values for a new calibrator lot from the data given on the package insert.

► To delete a calibrator definition

1. Click Configuration on the navigation bar.
2. Double-click Calibrators in the Definitions group.
3. Click the ID tab.
4. Select a calibrator from the list.
5. Click Delete.
6. Click Yes in the Confirm Delete dialog box.

Tip

If you decide not to delete a selected calibrator after pressing the Delete key, you can click No or Cancel in the Confirm Delete dialog box.

Preconditions

- You have sufficient user access privileges.
- The system is in Standby or Sleeping mode.
- The rack containing the calibrator is *not* on board.
- There are no calibration results that were obtained on the basis of this calibrator.
- The calibrator is no longer assigned to a test. You first need to assign a new calibrator to the test (Configuration / Tests / General). Assigning a new calibrator, automatically deletes calibration results that were obtained on the basis of the previous calibrator.

Quality controls

Validating tests to ensure the integrity of your system

This chapter tells you how to load, set up, and request quality controls, and how to analyze quality control results.

In this chapter

Chapter 11

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  Viewing missing and blocked controls B-165
  Reviewing a control definition B-166
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Requesting controls B-168
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  Deleting a control request B-169
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About controls

The *Cedex Bio HT* Quality Control (QC) function supports established control rules that can be customized to satisfy individual requirements.

It supports all test groups including routine chemistries, specific proteins, and electrolytes. There are three control modes, each with its own set of rules.

Control modes

Three modes are recognized: accuracy, precision, and limit. Each is characterized by one or more rules; when the rule is broken, a flag is generated on the control result.

Control mode	Checks whether control results...	Rules and flags
Precision	Have violated rules according to the Shewhart procedure (commonly known as the Westgard rules). Depending on the rules violated, a systematic or random error may have been generated.	Westgard rules: R(1)2s, R10x, R(1)3s, R(2)2S, R(4s), R4(1s)
Accuracy	Are within a range defined by the assigned value of an assayed control and a permissible deviation. When control results are out of range, a systematic error may have been generated.	>ACC RNG (accuracy range exceeded)
Limit	Have exceeded either upper or lower limits.	>Up Limit, <Low Limit (upper or lower limit exceeded)

You can view a single control with any combination of the precision, accuracy and limit modes, if the appropriate definitions are made in the control definition.

Priority of quality control modes

The priority of quality control modes is:

1. Precision
2. Accuracy
3. Limit

Number of controls

Each test can have up to six controls at one time. Only the first three can be used as precision controls.

Controls and test definitions

The test definition defines which controls are used for a test and how often the control is run. You can modify the test definition in Configuration / Tests / Control.

Control flags and test results

A control is valid for one test. A control result that meets all the rules for a particular test does not generate any flags and all test results can be automatically accepted, if this option is enabled.

A control result that falls outside the defined limits generates a flag on that control result. This means that all the results for this test since the last unflagged control require validation. Typically this involves rerunning the control; otherwise, you may have to use other controls or recalibrate the test.

Accepted control results are automatically removed from the Validate tab in the Results work area and put into the controls archive in the Quality Control tab in Results.

Controls and calibrations

All controls depend on calibrations. If a calibration is flagged, the controls that depend on it are not accepted automatically; they are assigned an “unaccepted calibration” flag.

Racks and controls

If the tubes containing your controls are barcoded, put them into the correct rack (with the barcode showing) and load the rack onto the instrument.

If your system is not configured to use barcodes, use one of these methods:

- Rack positions may have been previously defined for controls (using Configuration / Lab / Reserve Positions). Place the controls in the pre-defined positions and load the rack.
- Use the Place Items (or Sample Handling) dialog box to assign rack positions to the controls. Place the controls in the defined positions and load the rack. The rack positions that you assign in this way are cleared at the next Begin of Day, provided the associated results were accepted and the racks are not on board.

Control intervals

Controls are run automatically according to the control interval defined in Configuration. You can also request controls manually in the Orders work area.

Printing control reports

“Printing Quality Control reports” on page B-56

Controls at a glance

Use the tables below to locate specific tasks by work area and tab.

Work area	Tab	Tasks
Status	Missing & Blocked	• Review missing controls for the current work load.
	Samples	• View controls on board; color shows the status. • Click a position to display the details for the selected control.
	Test Status	• List tests with QC interval, controls and their rack positions, and whether the control was accepted.
Orders	Worklist	• Review the status of pending control requests.
	Quality Control	• Review individual control requests. • Request a control. • Delete a control request.
Results	Validate	• Review flagged control results. • Display the Control Detail dialog and then Rate info. • Accept unaccepted control results or rerun the control. • Delete a control result (to exclude it from statistics).
	Quality Control	• Review controls by test, or by controls. • Review QC details dialog. • Specify a date range for a listed control. • Switch between Precision, Accuracy and Limit. • Review statistics for a selected control. • Exclude a single control result from statistics. • Monitor control values for a test over time. • Print Quality Control reports.

Use the following table to locate specific tasks in the Configuration work area:

Icon	Tab	Tasks
Tests	Control	• Assign controls to tests. • Specify a control interval for a test and whether QC results are checked for this test.
Controls	Lot	• Specify a control lot number and assigned values for a selected control and test. • Create a new non-Roche control definition.
Database	QC Mode	• Specify which QC rules are checked for all tests.
Result Handling	Quality Control	• Specify the automatic handling of flagged and unflagged quality control results.

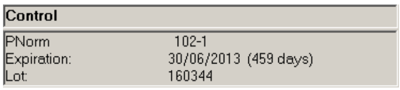
Reviewing the status of controls on board

You can check the status of the controls on board, to find out if they need replacing, for example.

► To view the controls on board

1. Click Status on the navigation bar.
2. Click the Samples tab.

   Samples, controls, and calibrators are displayed graphically. The legend QC indicates the presence of a control.
3. Double-click a control to display details about that control. For example:



Control	
PNorm	102-1
Expiration:	30/06/2013 (459 days)
Lot:	160344

Tip

Double-click the rack number to display name and position of all controls on that rack.

What if?

The control is expired	Replace the expired control with one that is not expired. *"To manually update lot specific control values" on page B-184*
The control is empty	Replace the control. Make sure that the lot number is the same as the previous control.
The control is blocked	One or more of the tests for this control is not available, for example, the test cassette is empty. Replace or load the cassette(s) as required.
The control is not on board	Load the required control. Make sure that the lot number of the control you load is the same as that specified in the control detail.
The control definitions are missing	The system has detected a control, but the control definition is missing or incomplete. *"Loading and deleting control definitions" on page B-181*

Viewing rack positions for controls

Typically, controls have preassigned rack positions on sample racks that you should use. You can also specify a location for a particular control, for example, if you intend to run control on a test that you do not run very often.

► To view rack positions for controls

1. Click Status on the navigation bar.
2. Click the Sample tab.

Or:

1. Click in the toolbar to open the Place Items dialog box.

2 Select a rack from the Samples on Rack list and check the positions.

👁 *"To load a control if rack positions have been predefined" on page B-169*

Tip

Use Configuration / Lab / Reserve Positions to check the reserved positions.

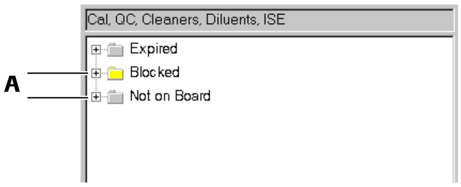
Viewing missing and blocked controls

If controls are requested and one or more of the required control(s) are not on board, the missing controls are listed on the Missing & Blocked tab in the Status work area, and also on the Worklist tab in the Orders work area.

► To view missing and blocked controls

1 Click Status on the navigation bar.

2 Click the Missing & Blocked tab.

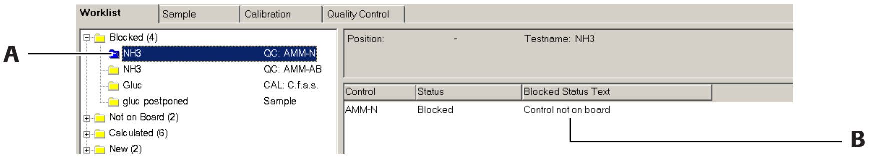

Cal, QC, Cleaners, Diluents, ISE
Expired
Blocked
Not on Board
A

A *Click ⊞ to open the folder. Controls are listed with their last rack number and position.*

Alternatively:

1 Click Orders on the navigation bar.

2 Click the Worklist tab.


Worklist
Sample
Calibration
Quality Control
Blocked (4)
NH3 QC: AMM-N
NH3 QC: AMM-AB
Gluc CAL: C.f.a.s.
gluc postponed Sample
Not on Board (2)
Calculated (6)
New (2)
Position: -
Testname: NH3
A
B

Control	Status	Blocked Status Text
AMM-N	Blocked	Control not on board

A *Double-click the control to display information on the status of this control.*

B *The Blocked Status Text gives the reason why the control is blocked.*

Reviewing a control definition

A control definition contains information about a control and the tests for which it is used.

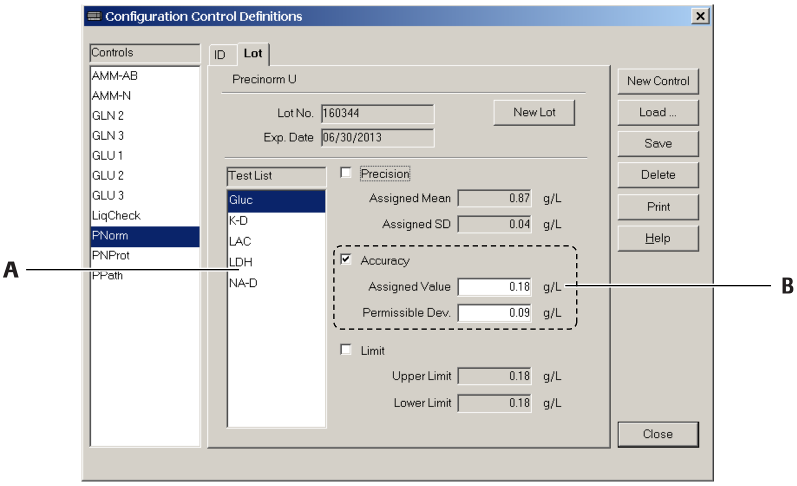
► To review a control definition

1 Click Results on the navigation bar.

2 Click the QC tab.

3 Double-click a control name.

The Control Definition dialog box is displayed.


Configuration Control Definitions
Controls
AMM-AB
AMM-N
GLN 2
GLN 3
GLU 1
GLU 2
GLU 3
LiqCheck
PNorm
PNProt
PPath
ID
Lot
New Lot
Test List
Gluc
K-D
LAC
LDH
NA-D
New Control
Load ...
Save
Delete
Print
Help
Close
A
B

Precinorm U

Lot No. 160344

Exp. Date 06/30/2013

☐ Precision

Assigned Mean 0.87 g/L

Assigned SD 0.04 g/L

☑ Accuracy

Assigned Value 0.18 g/L

Permissible Dev. 0.09 g/L

☐ Limit

Upper Limit 0.18 g/L

Lower Limit 0.18 g/L

A *List of tests that use the selected control.*

B *In this example, the Accuracy QC mode is selected, and the assigned values are entered.*

Loading controls on board

If the tubes containing your controls are barcoded, place them on a rack (with the barcode showing) and load the rack onto the instrument.

If your system is not configured to use barcodes, follow one of the following procedures:

► To load a control if rack positions have been predefined

Rack positions may have been previously defined for controls using Configuration / Lab / Reserve Positions.

1. Click Status on the navigation bar.
2. Click the Samples tab.
3. Identify the rack and position of the control from the graphic.
4. Remove the rack from its slot.
5. Place the control in the specified position on the rack.
6. Load the rack into an available slot.

Tip

You can use Place Items to identify rack and position of the controls. You need to use this method if the rack is not on board when you start the procedure.

► To load a control if rack positions have not been predefined

1. Click Orders on the navigation bar.
2. Click the Quality Control tab.
3. Select All in the QC list.
4. Select the required control from the Controls/Test Summary list.
5. Choose View > Sample Handling.
6. Specify a value in the Rack column for the rack number.
7. Specify a value in the Pos column for the position on the rack.
8. Click OK.
9. Place the control on the rack.
10. Load the rack into an available slot.

Tip

You can use the Place Items dialog box instead of Sample Handling to assign controls to rack positions.

Requesting controls

Most controls are run automatically according to the intervals specified for the control in Configuration / Tests / Control. You can choose to run controls automatically after a calibration, and when a specified time period has elapsed or a number of tests have been run.

You can request a control manually at any time.

Recommendation

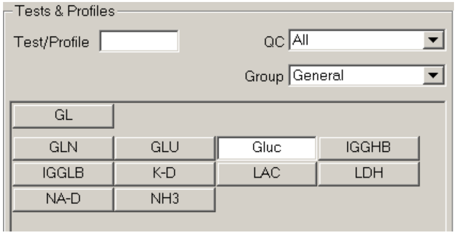
You should not accept a flagged control result without further investigation.

Requesting a control manually

You can request a control at any time in the Orders work area.

► **To request a control manually**

1. Click Orders on the navigation bar.
2. Click the Quality Control tab.
3. In the Tests & Profiles group, click the test for which you want to request a control.



Tests & Profiles

Test/Profile

QC All

Group General

4. Click Save.

Tips

- Step 3 - In the Control/Test summary, the name of the test is added to the folder of the required control. (White symbols indicate new tests, gray symbols point to tests with results.)
- Only controls with current requests are displayed in the Control/Test Summary.
- Controls for a test are run automatically depending on the test definition.

What if?

I can't see the test I want

- In the Tests & Profiles group, select All from the QC list, or ensure that the group you have selected contains the required test.
- Click the Class/Group button in Configuration / Tests to find out which tests are assigned to which groups.

Deleting a control request

If you find that you do not want to run a control, you can delete the request.

► To delete a control request

1 Click Orders on the navigation bar.

2 Click the Quality Control tab.

3 In the Control/Test Summary, click the ⊞ to open a control folder.

4 Right-click the required test name, and choose Delete from the context menu.

Tip

Controls that are running are grayed out and you cannot delete them.

Reviewing and validating control results

If a control result falls outside the defined limits, a flag is created and you must validate the result. You should not accept a flagged control result without further investigation. Controls that run without creating flags are accepted automatically, provided the system is configured to do so (Configuration / Result Handling / Quality Control).

To review flagged control results, click the Validate tab in the Results work area.

To review control results that have been accepted either automatically or manually, click the Quality Control tab in the Results work area.

Reviewing controls for validation

Controls that require validation are displayed in the Validate tab in the Results work area.

► To review controls for validation

1 Click Results on the navigation bar.

2 Click the Validate tab.

3 Select the required test from the To Validate folder.

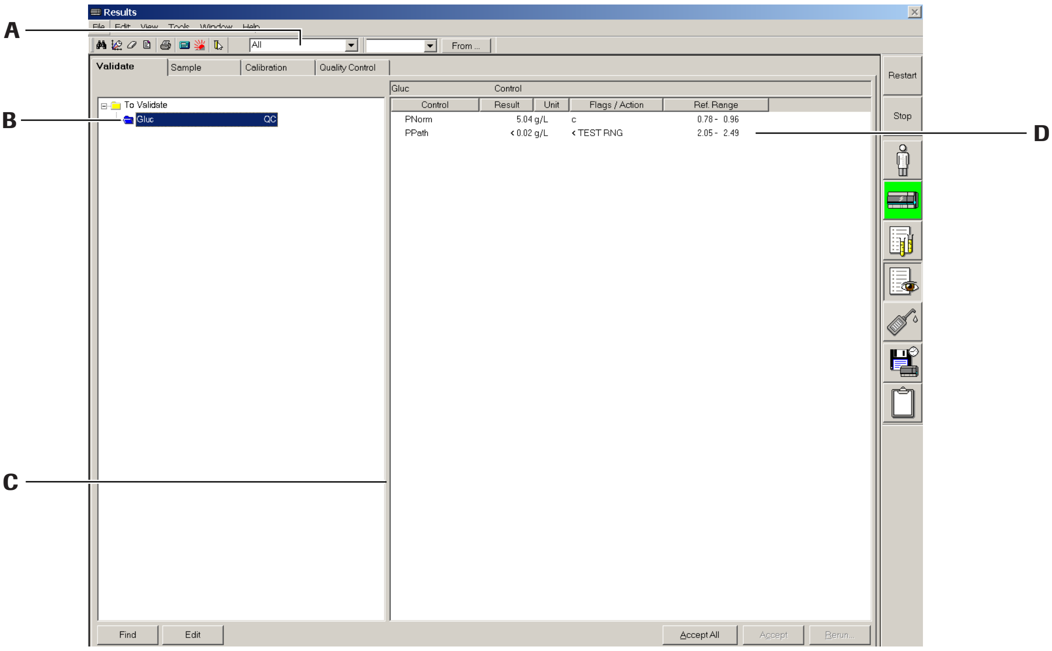
4 Perform the actions required from the flags generated. (Double-click the control line to display details on the result.)

5 Click the appropriate button.

Accept: Accepts the selected control result.

Accept All: Accepts all control results for selected test.

Rerun: Rerun the control. The current results are deleted.


A
B
C
D
Results
File Edit View Tools Window Help
All
From ...
Validate
Sample
Calibration
Quality Control
To Validate
Gluc QC
Restart
Stop
Find
Edit
Accept All
Accept
Rerun...

Gluc Control

Control	Result	Unit	Flags / Action	Ref. Range
PNorm	5.04	g/L	c	0.78 - 0.96
PPath	< 0.02	g/L	< TEST RNG	2.05 - 2.49

A *From the list, select whether you want to display all results (All) or only the unaccepted results (Unaccepted).*

B *The selected control.*

C *To resize the columns, position your cursor here and click and drag the divider.*

D *This control is flagged. Double-click for more information.*

Tips

- Double-click the test name in the Validate list to view details about the control order.
- Double-click the control result to view additional details about the control.
- For a flagged control, select the control, then perform these steps:
    - Follow the recommended action for each flag.

      👁 *Chapter 12, “Result flags”*
    - Check the assigned lot number of the control against the actual lot number on the package insert. If these are different, rerun the control with the correct control lot.
- A paper clip at the beginning of the line indicates that a comment has been entered in the Details dialog box.)
- Press F1 to display Help for this tab.

Reviewing control results

Use the Quality Control tab in the Results work area to review quality control results.

► To review control results

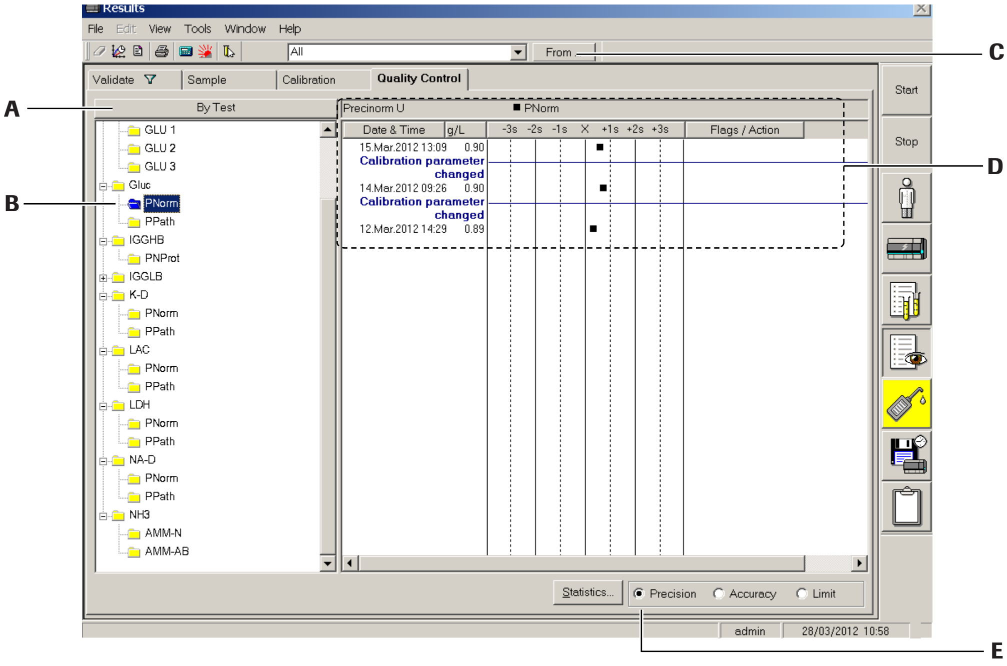
1 Click Results on the navigation bar.

2 Click the Quality Control tab.

3 Click the column header until it shows By Test.

4 Click the ⊞ to open a test folder.

5 Use the From button on the toolbar to define a period to reduce the number of results displayed.


Results
File
Edit
View
Tools
Window
Help
All
From
Validate
Sample
Calibration
Quality Control
Start
Stop
By Test
GLU 1
GLU 2
GLU 3
Gluc
PNorm
PPath
IGGHB
PNProt
IGGLB
K-D
PNorm
PPath
LAC
PNorm
PPath
LDH
PNorm
PPath
NA-D
PNorm
PPath
NH3
AMM-N
AMM-AB
Precinorm U
■ PNorm
Date & Time
g/L
-3s
-2s
-1s
X
+1s
+2s
+3s
Flags / Action
Statistics...
Precision
Accuracy
Limit
admin
28/03/2012 10:58
A
B
C
D
E

15.Mar.2012 13:09 0.90
Calibration parameter changed
14.Mar.2012 09:26 0.90
Calibration parameter changed
12.Mar.2012 14:29 0.89

● Precision ○ Accuracy ○ Limit

A *Click the column header to organize the information by controls or by tests.*

B *The folder for the selected test. Each test can have up to six controls.*

C *Use From to specify or modify the date range. Only the results within the specified range are listed in the Results list.*

D *Results are displayed in this area. Each control has a unique symbol.*

E *Select the Precision, Accuracy, or Limit QC mode. (The available options depend on the control definition for the selected test.)*

“Understanding control results” on page B-176

Reviewing control statistics

► To review statistics for a specified control

1 Click Results on the navigation bar.

2 Click the Quality Control tab.

3 Select the By Control view.

4 Select the required control from the By Control list.

5 Click Statistics.

6 Select the required control mode using one of the option buttons.

The Statistics dialog displayed depends on the selected mode.

► To review statistics for the controls used by a test

1 Click Results on the navigation bar.

2 Click the Quality Control tab.

3 Select the By Test view.

4 Select the required test from the By Test list.

5 Click Statistics.

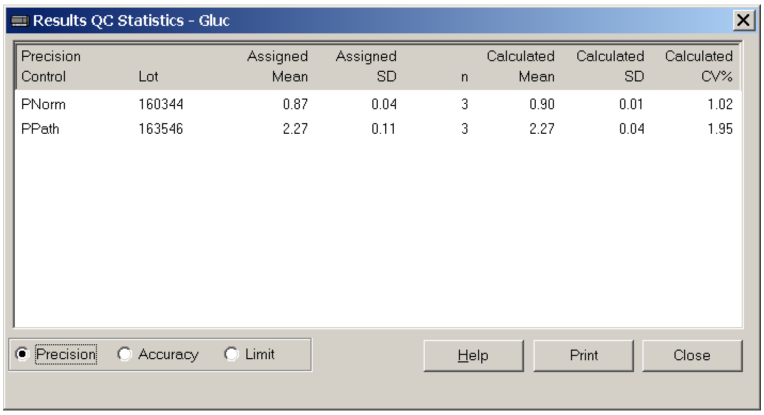
6 Select one of the control mode buttons.

The Statistics dialog displayed depends on the mode selected.

Precision controls

The Statistics dialog box shows the assigned and calculated values for the mean and standard deviation of selected results for each control.

The following example shows precision controls when a control is selected in the By Control list.

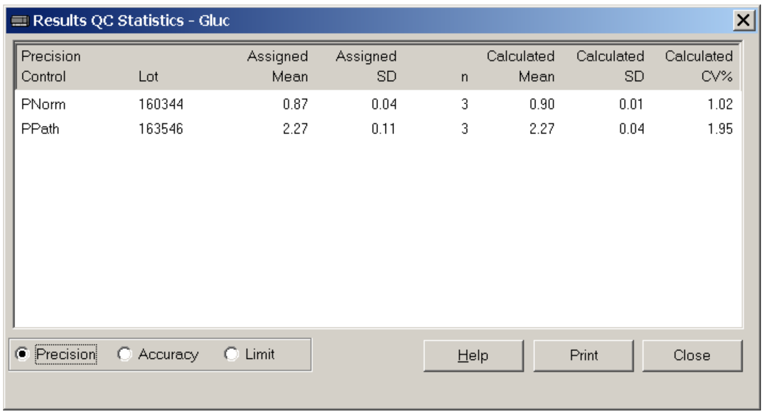


Results QC Statistics - Gluc

Precision Control	Lot	Assigned Mean	Assigned SD	n	Calculated Mean	Calculated SD	Calculated CV%
PNorm	160344	0.87	0.04	3	0.90	0.01	1.02
PPath	163546	2.27	0.11	3	2.27	0.04	1.95

● Precision ○ Accuracy ○ Limit

The following example shows precision controls when a test is selected in the By Test list



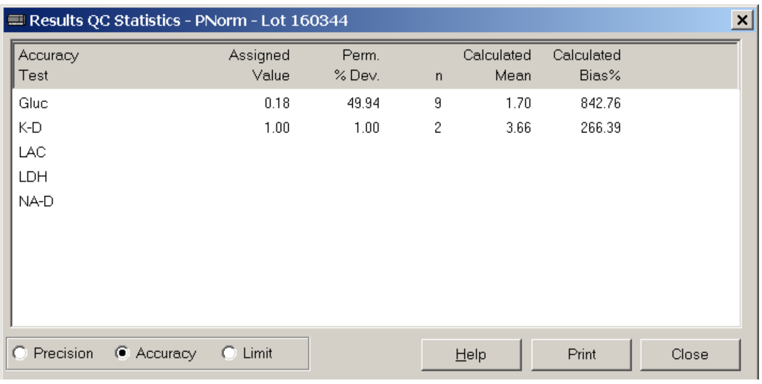
Results QC Statistics - Gluc

Precision Control	Lot	Assigned Mean	Assigned SD	n	Calculated Mean	Calculated SD	Calculated CV%
PNorm	160344	0.87	0.04	3	0.90	0.01	1.02
PPath	163546	2.27	0.11	3	2.27	0.04	1.95

● Precision ○ Accuracy ○ Limit

Accuracy controls

The Statistics dialog box shows the assigned value, permissible deviation, the number of results in the statistic (n), the calculated mean, and the calculated bias for the selected results for each control.



Results QC Statistics - PNorm - Lot 160344

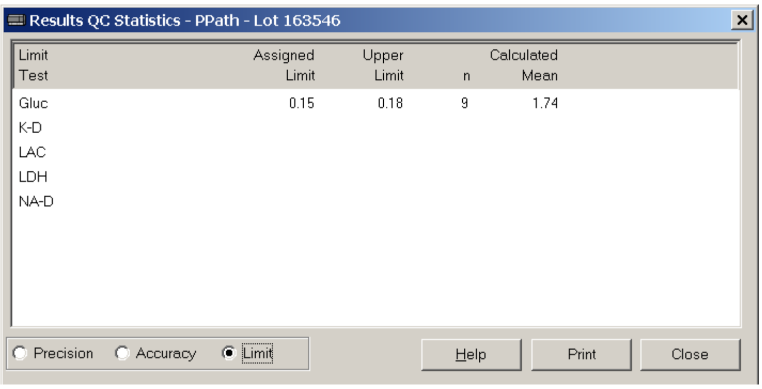
Accuracy Test	Assigned Value	Perm. % Dev.	n	Calculated Mean	Calculated Bias%
Gluc	0.18	49.94	9	1.70	842.76
K-D	1.00	1.00	2	3.66	266.39
LAC					
LDH					
NA-D					

○ Precision ● Accuracy ○ Limit

Help
Print
Close

Limit controls

The Statistics dialog box shows the predefined lower and upper limits, the number of results in the statistic, and the calculated mean.



Results QC Statistics - PPath - Lot 163546

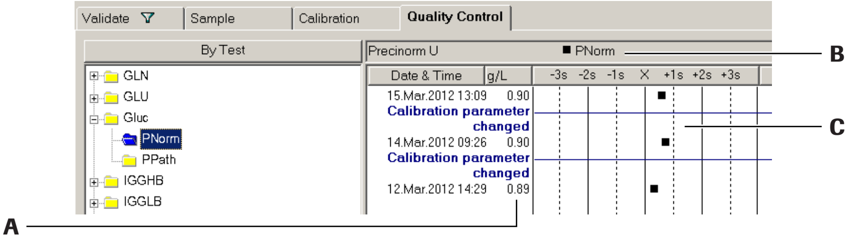
Limit Test	Assigned Limit	Upper Limit	n	Calculated Mean
Gluc	0.15	0.18	9	1.74
K-D				
LAC				
LDH				
NA-D				

○ Precision ○ Accuracy ● Limit

Help
Print
Close

Understanding control results

Each result for the selected test is displayed numerically and as a point on a graph. The type of graph depends on which QC mode (precision, accuracy, or limit) is selected.



Validate
Sample
Calibration
Quality Control
By Test
GLN
GLU
Gluc
PNorm
PPath
IGGHB
IGGLB
Precinorm U
PNorm
Date & Time
g/L
-3s
-2s
-1s
X
+1s
+2s
+3s
A
B
C

Date & Time	g/L
15.Mar.2012 13:09	0.90
Calibration parameter changed	
14.Mar.2012 09:26	0.90
Calibration parameter changed	
12.Mar.2012 14:29	0.89

A *Numerical control results*

B *Each control has its own symbol*

C *Graphical display of a result in terms of the mean and standard deviation (for precision controls)*

The graphical display above shows the results from a single precision control run over a period of time. Vertical lines show the relative positions of the mean and one, two, or three standard deviations on either side of the mean.

Tips

- The date for unaccepted controls is displayed as a dashed line.
- A paper clip at the beginning of the line indicates that a user comment has been entered in the detail dialog.
- A dotted line across the graph indicates that the control range parameters were changed.
- To view a different QC mode, select Precision, Accuracy, or Limit in this window.
- Position your cursor over a control symbol to display the control name and the Westgard rule (if flagged) or the result (if not flagged).

Multiple controls

Several controls can be displayed at the same time, depending on the test selected. Each control has its own unique symbol.

With multiple controls displayed, each graph is scaled to its own reference values. For example, for a precision control, the graphs are scaled to the respective mean and standard deviation for each control.

Tips

- Take care when making comparisons, because different controls have different scales.
- When you select a test, only the first three controls are displayed, even though up to six controls may have been run. (Only the first three results are used for statistics.)

► To review precision controls

1 Click Results on the navigation bar.

2 Click the Quality Control tab.

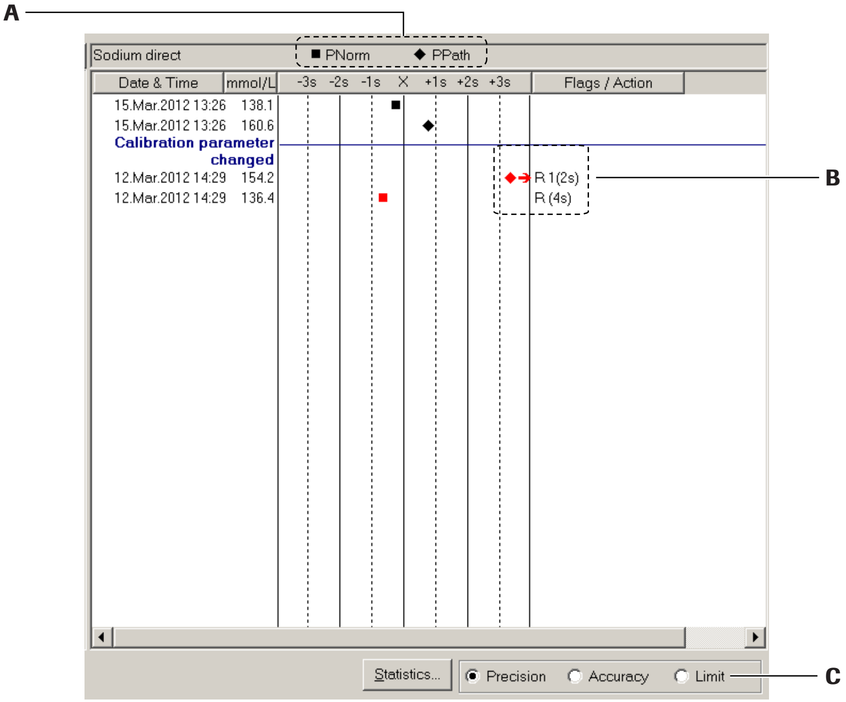
3 Click the button at the top of the column until it shows By Test.

4 Click ⊞ to open a test folder.

5 Use the From button on the toolbar to define a period to reduce the number of results displayed.

6 Select the Precision option (if available for the selected control).

The results are displayed to the left of the graph; the graphical display looks like this:



Date & Time	mmol/L	Flags / Action
15.Mar.2012 13:26	138.1	
15.Mar.2012 13:26	160.6	
Calibration parameter changed		
12.Mar.2012 14:29	154.2	R 1(2s)
12.Mar.2012 14:29	136.4	R (4s)

A *Legend showing the symbols for each control.*

B *Control point(s) outside 3 standard deviations.*

C *If a control mode is not available for this test, it is grayed out.*

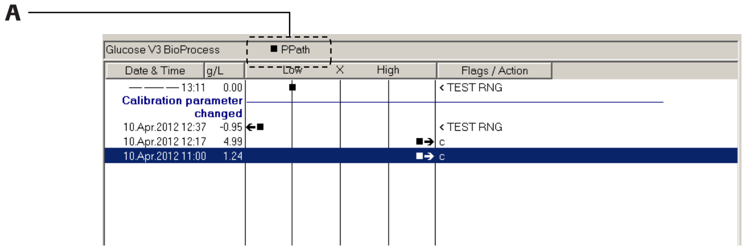
Tips

- Red symbols represent flagged results.
- Gray entries represent results that either were excluded from the statistics or have the status Deleted (a rerun was ordered).

► To review accuracy controls

1. Click Results on the navigation bar.
2. Click the Quality Control tab.
3. Click the button at the top of the column until it shows By Test.
4. Click ⊞ to open a test folder.
5. Select a control.
6. Use the From button on the toolbar to define a period to reduce the number of displayed results.
7. Select the Accuracy option (if available for the selected control).

The results are displayed to the left of the graph; the graphical display looks like this:



Glucose V3 BioProcess ■ PPath

Date & Time	g/L	Low X High	Flags / Action
— — — 13:11	0.00	■	< TEST RNG
Calibration parameter changed			
10.Apr.2012 12:37	-0.95	←■	< TEST RNG
10.Apr.2012 12:17	4.99	■→	c
10.Apr.2012 11:00	1.24	■→	c

A *Legend showing the symbols for each control.*

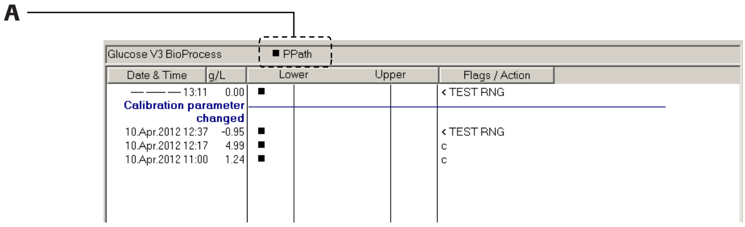
Tips

- Red symbols represent flagged results.
- Gray entries represent results that either were excluded from the statistics or have the status Deleted (a rerun was ordered).
- For accuracy controls the graph is scaled relative to the assigned value and the high and low values associated with the permissible deviation. Again, each control has its own symbol.

► To review limit controls

1. Click Results on the navigation bar.
2. Click the Quality Control tab.
3. Click the button at the top of the column until it shows By Test.
4. Click ⊞ to open a test folder.
5. Select a control.
6. Use the From button on the toolbar to define a period to reduce the number of displayed results.
7. Select the Limit option (if available for the selected control).

   The results are displayed to the left of the graph; the graphical display looks like this:



Glucose V3 BioProcess ■ PPath

Date & Time	g/L	Lower Upper	Flags / Action
— — — 13:11	0.00	■	< TEST RNG
Calibration parameter changed			
10.Apr.2012 12:37	-0.95	■	< TEST RNG
10.Apr.2012 12:17	4.99	■	c
10.Apr.2012 11:00	1.24	■	c

A *Legend showing the symbols for each control.*

Tips

- Red symbols represent flagged results.

- Gray entries represent results that either were excluded from the statistics or have the status Deleted (a rerun was ordered).

Setting up controls

Information about a control is stored in the control definition and in the test definition. The control definition is loaded from disk, or can be set up manually in Configuration / Tests / Control.

Loading and deleting control definitions

If you receive an update to a control definition, use this procedure to load the new control definition.

1. Load the control definition.
2. Assign the control to tests.
3. Update the lot information and values manually or use the barcode pen or handheld barcode scanner.

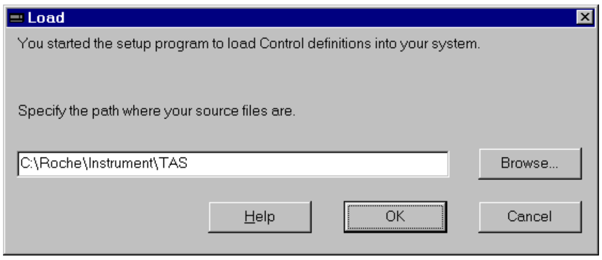
► To load a new control definition

1 Click Configuration on the navigation bar.

2 Double-click Controls in the Definitions group.

3 Click Load.

The Load dialog box is displayed.



Load

You started the setup program to load Control definitions into your system.

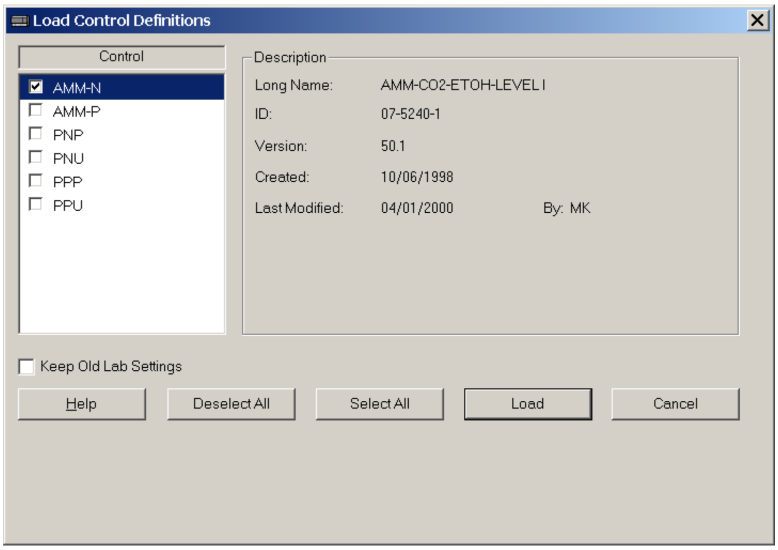
Specify the path where your source files are.

C:\Roche\Instrument\TAS

4 Click Browse and choose the drive and directory where the required control definition is located. By default, the C:\Roche\Instrument\TAS path is selected. Alternatively, type the complete path.

5 Click OK.

The Load Control Definitions dialog box is displayed.



☑ AMM-N
☐ AMM-P
☐ PNP
☐ PNU
☐ PPP
☐ PPU

Long Name: AMM-CO2-ETOH-LEVEL I
ID: 07-5240-1
Version: 50.1
Created: 10/06/1998
Last Modified: 04/01/2000 By: MK

☐ Keep Old Lab Settings

6 Select the required controls.

7 Click Load.

A progress indicator is displayed.

8 When the controls have been loaded, click Cancel o close the Load Control Definitions dialog box.

9 Select the control from the Control list.

10 Click the Lot tab to review existing lot information or to create a new lot.

“Updating lot specific values for a control” on page B-184

11 Click Save.

12 Click Close.

Tips

- You must have the correct user access level to load controls.
- The system must be in Sleeping or Standby mode.
- Use the New Control button to create a control definition manually.
- Controls loaded from Roche disks have IDs with the format 07-xxxx-xx. You cannot change this ID.
- If you work with a barcode pen or handheld barcode scanner, click Save after step 8 and then read the barcode with the pen or scanner.

► To delete a control definition

1 Click Configuration on the navigation bar.

2 Double-click Controls in the Definitions group.

3 Click the ID tab.

4 Select a control from the list.

5 Click Delete.

6 Click Yes in the Confirm Delete dialog box.

Tips

- If you decide not to delete a selected control after pressing the Delete key, you can click No or Cancel in the Confirm Delete dialog box.
- You can press the Delete key instead of clicking Delete.

Preconditions

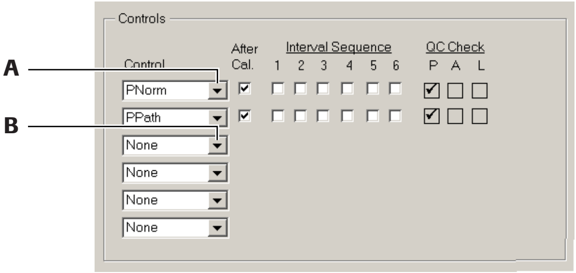
- You have sufficient user access privileges.
- The system is in Standby or Sleeping mode.
- The rack containing the control is *not* on board.
- The control is no longer assigned to a test. You first need to assign a new control to the test or define that no control is required (Configuration / Tests / Control). Assigning a new control automatically deletes control results that were obtained on the basis of the previous control.

Assigning controls to tests

When you have loaded a control definition, it can be assigned to the associated tests.

► To assign a control to a test

1. Click Configuration on the navigation bar.
2. Double-click Tests in the Definitions group.
3. Select the required test from the Installed Tests list.
4. Click the Control tab.
5. Select the required control.



Control	After Cal.	1	2	3	4	5	6	P	A	L
PNorm	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐
PPath	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐
None										
None										
None										
None										

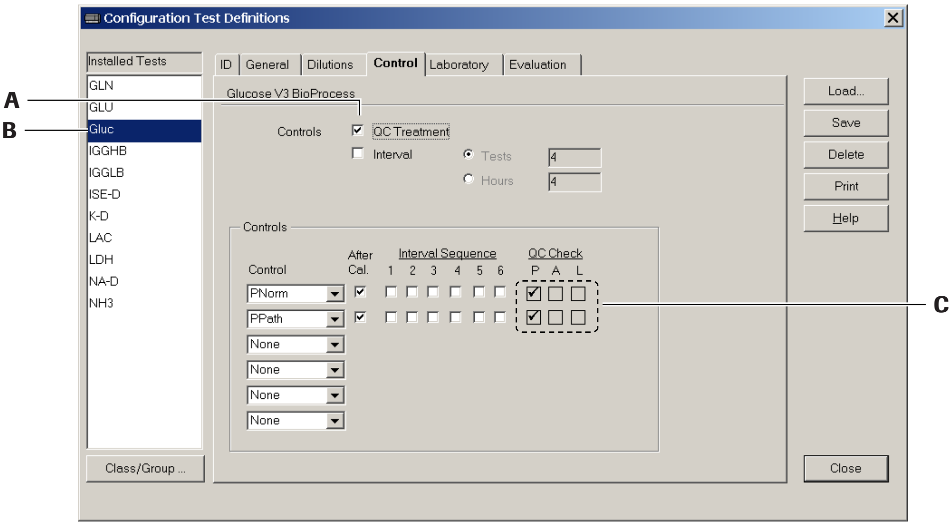
A *Click here to list all the controls, then select the one you want to assign.*

B *No control defined. Click here to list all the controls, then select the one you want to assign.*

6. Select the QC treatment check box to enable the QC rules and ranges for this test. The control results are automatically listed in the Results work area as they are calculated.

   If you clear this check box, QC rules and ranges are not checked.

   "Specifying control intervals" on page B-187


Configuration Test Definitions
Installed Tests
GLN
GLU
Gluc
IGGHB
IGGLB
ISE-D
K-D
LAC
LDH
NA-D
NH3
Class/Group ...
ID
General
Dilutions
Control
Laboratory
Evaluation
Glucose V3 BioProcess
Controls
☑ QC Treatment
☐ Interval
● Tests 4
○ Hours 4
Controls
Control
After Cal.
Interval Sequence
1 2 3 4 5 6
QC Check
P A L
PNorm ☑ ☐ ☐ ☐ ☐ ☐ ☐ ☑ ☐ ☐
PPath ☑ ☐ ☐ ☐ ☐ ☐ ☐ ☑ ☐ ☐
None
None
None
None
Load...
Save
Delete
Print
Help
Close
A
B
C

A *Specifies whether control results are checked for QC rules and ranges.*

B *The selected test.*

C *Shows which QC modes are enabled.*

Updating lot specific values for a control

The procedure to update lot specific control values depends on whether you use a barcode pen or handheld barcode scanner or not.

► To manually update lot specific control values

1 Click Configuration on the navigation bar.

2 Double-click Controls in the Definitions group.

3 Select the required control from the Controls list.

4 Click the Lot tab.

Tests to which the control is assigned are listed here, provided a lot exists.

5 Click New Lot.

6 Type new values for the Lot No. (Lot Number) and Exp. Date (Expiration Date).

7 Click Save.

8 For each test, select the control mode and type the values for this mode.

9 Click Save.

Tips

- The lot number is up to ten characters.
- The format of the expiration date must be the same as that for the date in the bottom right-hand corner of the screen.
- When you have saved the lot number and expiration date, the tests that use the control are displayed in the Test list. Enter and save new control values for each test.

► To update lot specific values using the barcode pen or handheld barcode scanner

1 Click Configuration on the navigation bar.

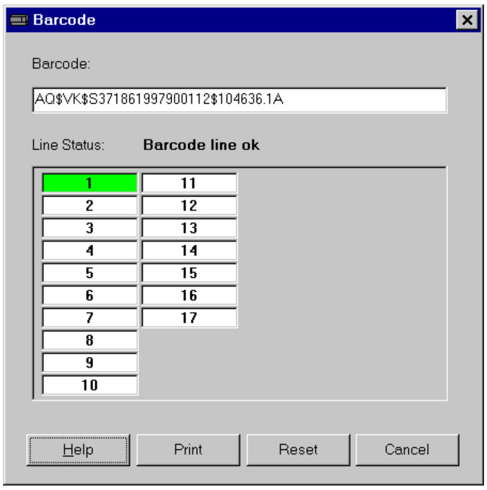
2 Choose File > Barcode from the menu bar or click ▥ in the toolbar.

The Barcode dialog box is displayed.

3 Run the barcode pen over the first barcode line of the calibrator or control information sheet or read the barcode with the handheld barcode scanner.

Note: The controls load as accuracy controls.

After reading the first line of barcode, the information is displayed on the Barcode dialog box.


Barcode
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
Help
Print
Reset
Cancel

Barcode: AQ$VK$S371861997900112$104636.1A

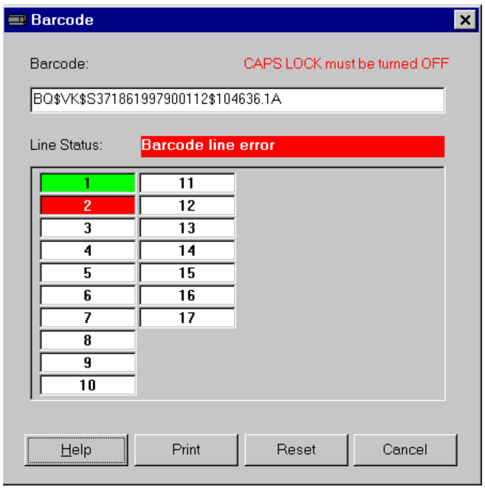
Line Status: **Barcode line ok**

The numbered boxes represent the barcode lines.

4 Read the rest of the barcode lines of the control information sheet.

5 Watch the Barcode dialog box.

Correctly read lines are represented by green boxes, lines with reading errors by red boxes and a message on the Line Status box of the Barcode dialog box.


Barcode
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
Help
Print
Reset
Cancel

Barcode: CAPS LOCK must be turned OFF

BQ$VK$S371861997900112$104636.1A

Line Status: **Barcode line error**

  - Using the barcode pen or handheld barcode scanner, re-read the barcode lines that are represented by a red box in the Line Status group of the Barcode dialog box.
  - Click Reset to delete all lines and restart the whole reading process.

6. When all lines are read correctly (all boxes are green), the Barcode dialog box closes automatically, and a message is displayed, informing you of the successful conclusion of the reading process.

Tips

- Using the barcodes to enter control values is only possible for *accuracy* values. All *precision* values first have to be established over a specified time period (typically 20 working days), and then to be entered manually.
- To read and edit the read lot information, use Configuration / Calibrators / Lot or Configuration / Controls / Lot.
- If you work with laboratory units other than the Roche standard units, the values read from the barcode sheet are automatically converted to your laboratory units, provided you specified the Lab Unit Factor (Configuration / Tests / Laboratory).
- Certain controls have more than 40 barcode lines. In this case, read in the first 40 barcode lines. Then reopen the Barcode dialog box to read in the rest of the barcode lines.

Turning control rules on and off

If you need to run controls without using the control rules, you can turn off control rules in the test definition.

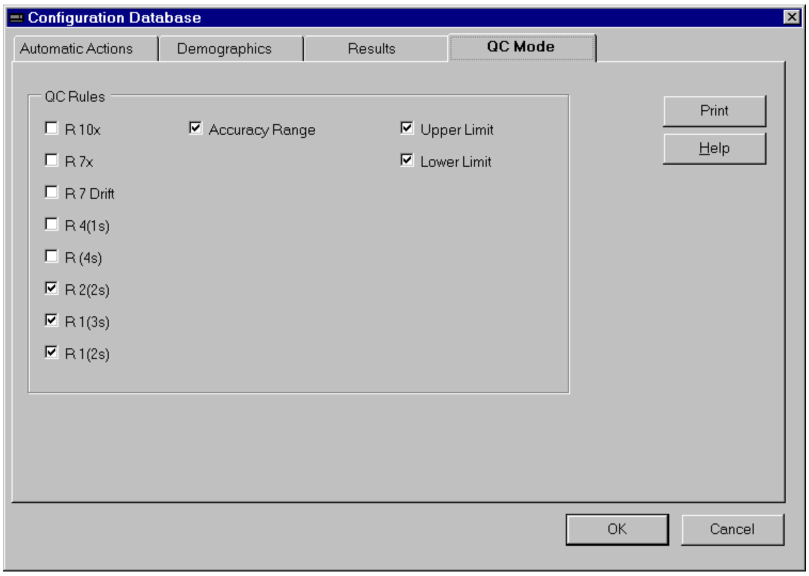
► To turn control rules off for a specific test

1. Click Configuration on the navigation bar.
2. Double-click Tests in the Definitions group.
3. Select the required test from the Installed Tests list.
4. Click the Control tab.
5. Clear the QC treatment box.
6. Click Save.

► To specify which QC rules are checked

1. Click Configuration on the navigation bar.
2. Double-click Database in the System group.

3 Click the QC Mode tab.



QC Rules

☐ R 10x
☐ R 7x
☐ R 7 Drift
☐ R 4(1s)
☐ R (4s)
☑ R 2(2s)
☑ R 1(3s)
☑ R 1(2s)
☑ Accuracy Range
☑ Upper Limit
☑ Lower Limit

4 Select the check box for each rule, as required.

5 Click one of the following:

- OK, to save your changes for all the tabs in this dialog box
- Cancel, to close the dialog box without making any changes

Tips

- This dialog applies to the system as a whole. That is, if a rule is checked in this dialog, it is potentially available for any control on a test, if configured.
- If you clear the check box for a rule, that rule is not available for any control on any test on the instrument.

Specifying control intervals

► To specify a control interval

1 Click Configuration on the navigation bar.

2 Double-click Tests in the Definitions group.

3 Click the Control tab.

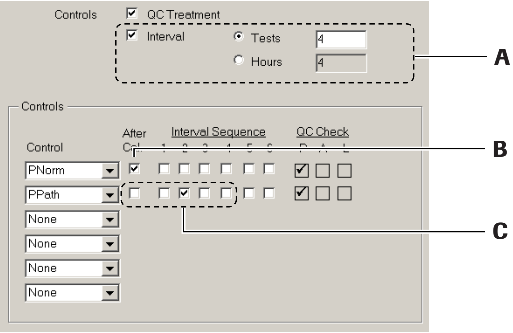
4 Select the Interval box.

5 Select either Tests and type the number of tests, or select Hours and type the number of hours.

6 Select After Cal, if you want a control to be run automatically after each calibration.

7 Select an interval sequence. If more than one control is defined, select consecutive Interval Sequence numbers.

8 Click Save.



Controls ☑ QC Treatment

☑ Interval ● Tests 4

○ Hours 4

Controls

Control	After Cal	Interval Sequence 1	2	3	4	5	6	QC Check P	A	L
PNorm	☑	☐	☐	☐	☐	☐	☐	☑	☐	☐
PPath	☐	☐	☑	☐	☐	☐	☐	☑	☐	☐
None										
None										
None										
None										

A *An interval can be defined as a number of tests or a number of hours.*

B *This control is automatically run after each calibration.*

C *This control is run after two intervals (8 tests).*

Tips

- A control can be run automatically after each calibration. You can set additional control intervals based on time (Hours), or on the number of tests run.
- The interval is reset after the control is run.
- The QC Check columns tell you which QC modes are on for each control. These are defined in Configuration / Controls / Lot.

Loading a non-Roche control

If you want to use a non-Roche control, you have to set it up and assign it to tests in this sequence:

1. Create a control definition.
2. Assign the control to tests; for each test, specify an interval sequence.
3. For the tests to which the control is assigned, specify the precision, accuracy, and limit values.

These procedures are detailed below.

► To define a non-Roche control

1 Click Configuration on the navigation bar.

2 Double-click Controls in the Definitions group.

3 Click the ID tab.

4 Click New Control to clear the text boxes.

5 Type a short name, ID, and long name.

6 Click Save.

7 Click the Lot tab.

8 Click New Lot.

9 Type a lot number and expiration date.

10 Click Save.

Tips

- Step 5 - Type the ID in the format 97-*nnnn-n*, where *n* is a number between 0 and 9.
- Step 10 - When you click Save, an empty Test list is displayed. Tests are listed here when you have assigned the non-Roche control to tests.
- To determine the statistical values required, you have to run the control as a sample enough times for statistical accuracy.

► To assign a non-Roche control to a test

1. Click Tests in the Definitions group.
2. Click the Control tab.
3. Select a test from the Installed Tests list.
4. Select the non-Roche control from one of the drop-down lists in the Controls group.
5. Specify interval sequence details for the control.
6. Click Save.
7. Click Close.

Tips

- Repeat this procedure for all tests that use the non-Roche control.
- Step 5 - The Precision (P), Accuracy (A), and Limit (L) boxes remain blank until you specify values for them in Configuration / Controls / Lot.

► To specify Precision, Accuracy, and Limit values for a control

1. Click Controls in the Definitions group.
2. Click the Lot tab.
3. Select the control from the Controls list.
4. Select a test from the Test list.
5. Specify Precision, Accuracy and Limit values.

   For a precision control:

   a. Select the Precision box.

   b. Specify values for the assigned mean and standard deviation.

   For an accuracy control:

   a. Select the Accuracy box.

   b. Specify values for the assigned value and the permissible deviation.

   For a limit control:

   a. Select the Limit box.

   b. Specify values for the upper and lower limits.

Tips

- Step 2 - Tests to which you have assigned the non-Roche control are now displayed in the Test list.
- Step 5 - You can select one or more of these options.
- Repeat this procedure for all the tests in the Test list.

Flags C

Part C provides details on all the flags that can be generated with results except those specifically related to the ISE module.

Result flags

Understanding flags on results

This chapter lists the flags that can be generated for the results of tests on samples, calibrations, or quality controls.

In this chapter *Chapter* **12**

About result flags C-5
Flags and recommended actions C-6
  >ACC RNG C-6
  >AG EXCESS C-6
  AIR FLUID C-6
  AIR ISECAL C-6
  c C-6
  C C-7
  CALC ERROR C-7
  <Critical Range C-8
  >Critical Range C-8
  CUR DIR C-8
  d C-8
  DARK ERR C-8
  EP UNSTAB C-9
  FP UNSTAB C-9
  HIGH ABS C-10
  HIGH ACT C-10
  HIGH BKG C-10
  ISE UNSTAB C-11
  <KIN READ C-11
  LOW ACT C-11
  <LOW LIM C-12
  LOW SIGNAL C-12
  NO FLUID C-12
  NO ISECAL C-12
  NON LINEAR C-13
  NON MONO C-13
  OUTLIERS C-13
  OUT OF RNG C-14

p ... C-14
P ... C-14
POL ERR ... C-14
POS (value) ... C-15
POSITIVE ... C-15
q ... C-15
Q ... C-15
r ... C-15
R ... C-16
R 1(2s) ... C-17
R 1(3s) ... C-17
R 2(2s) ... C-17
R (4s) ... C-17
R 4(1s) ... C-18
R7 ↓ Drift ... C-18
R7 ↑ Drift ... C-18
R 7x ... C-19
R 10x ... C-19
<REAG RNG ... C-19
>REAG RNG ... C-19
>REPL DEV ... C-20
<RR (value) ... C-20
>RR (value) ... C-20
SEG FLUID ... C-20
SEG ISECAL ... C-20
SOL 1 F DEV ... C-20
>STD DEV ... C-20
<TEST RNG ... C-21
>TEST RNG ... C-21
>UP LIM ... C-21
> ... C-22
∨ ... C-22
^ ... C-22

About result flags

Flags are displayed and printed together with the results. They are also displayed with the results in the Results and Orders work areas.

Flag groups

Flags are grouped according to the measurement method and the way the result is evaluated.

CAL	Flags from calibration measurement and result evaluation.
CNTL	Flags from quality control measurement and result evaluation.
RAT	Flags from calculated result (ratio) evaluation.
TEST	Flags from sample measurement and result evaluation.

Flag priority

Within each of the flag groups, a priority level is assigned to each flag, and it is the flag with the highest priority (with the lowest priority number) that is displayed.

Flag display

In the results lists on the tabs of the Results work area, only one flag is shown. To look at all generated flags, double-click the result, and the flags are explained in the Details dialog box.

For details on individual ISE flags and recommended actions, see

👁 *"Flags and user actions" on page F-41*

Flags and recommended actions

>ACC RNG

Meaning

Accuracy range.

For an accuracy control, the result is outside the permitted range.

Recommended action

1. Check if the correct control material has been used.
2. Repeat with fresh control.

Attributes

Priority: 53

Group: CNTL

>AG EXCESS

Meaning

Antigen excess.

The sample contains an excess antigen and a valid result cannot be calculated.

Recommended action

1. Rerun the test with postdilution.
2. If the flag occurs after dilution, rerun the test using a higher dilution factor.

Attributes

Priority: 29

Group: CAL, CNTL, TEST

AIR FLUID

“AIR FLUID” on page F-43

AIR ISECAL

“AIR ISECAL” on page F-43

c

Meaning

The result was calculated using an erroneous or corrected calibration which has been accepted.

Recommended action

- CNTL
  - Repeat calibration.
- RAT, TEST
  1. Review controls.
  2. Repeat calibration.

Attributes

Priority: 33

Group: CNTL, RAT, TEST

C

Meaning

Result calculated using an erroneous or corrected calibration which has not been accepted.

Recommended action

- CNTL
  1. Check that the correct calibrators have been used and that the calibrator cups are correctly positioned.
  2. Check that the correct Assigned Value is defined in Configuration / Calibrators / Lot.
  3. Repeat calibration.
- RAT, TEST
  1. Check calibration.
  2. Repeat calibration.

Attributes

Priority: 32

Group: CNTL, RAT, TEST

CALC ERROR

Meaning

- CAL

  Calculation error.

  Nonlinear standard curve cannot be calculated due to calibration error.
- CNTL

  Calculation error.

  Concentration could not be calculated.
- RAT

  Calculation error.

  Result could not be calculated.
- TEST

  Calculation error.

  Concentration could not be calculated.

Recommended action

- CAL
  1. Repeat calibration with fresh calibrators.
  2. If the calibrators were incorrectly positioned, replace the calibrators and repeat the calibration.
- CNTL
  - Repeat calibration and control.
- RAT
  1. Repeat calibration.
  2. Rerun sample with dilution.
- TEST
  - Repeat sample.

Attributes

Priority: 24

Group: CAL, CNTL, RAT, TEST

<Critical Range

Meaning

The result is below the critical low value.

Recommended action	Follow the laboratory procedure for critical value reporting.
Attributes	Priority: 56 Group: RAT, TEST

>Critical Range

Meaning	The result is above the critical high value.
Recommended action	Follow the laboratory procedure for critical value reporting.
Attributes	Priority: 57 Group: RAT, TEST

CUR DIR

Meaning	Curve direction. The direction of the calibration curve is incorrect.
Recommended action	**1** Check the detail of the calibration. **2** If the calibrators were incorrectly positioned, replace the calibrators correctly and rerun the calibration.
Attributes	Priority: 19 Group: CAL

d

Meaning	Deleted. Std. Result (or replicate) has been deleted.
Recommended action	• Request a new measurement.
Attributes	Priority: 40 Group: CAL

DARK ERR

Meaning	Dark error. The dark measurement taken for an FP test was higher than the test measurement.
Recommended action	**1** Repeat the measurement. **2** If the flag reappears, contact Roche Service.
Attributes	Priority: 2 Group: CAL, CNTL, TEST

EP UNSTAB

Meaning	Endpoint unstable. The absorbance values near the endpoint show unacceptable fluctuation.
Recommended action	• CAL

  1. Repeat with fresh calibrators if only calibration is flagged.
  2. If flag is on controls and samples also, or repeats on calibration, replace cassette.
- CNTL
  1. If only one control is flagged, repeat with fresh control.
  2. If flag on more than one control and sample, replace cassette.
- TEST
  1. Rerun diluted.
  2. If only one sample, repeat with fresh sample.
  3. If flag is on more than one sample, or repeats, replace cassette.

Attributes Priority: 16

Group: CAL, CNTL, TEST

FP UNSTAB

Meaning FP measurements unstable.

The result from the parallel or perpendicular intensity measurement was inconsistent.

Recommended action

- CAL
  1. Check the calibrator for air bubbles or foam and repeat the measurement.
  2. If the flag reappears, contact Roche Service.
- CNTL
  1. Check control for bubbles and repeat measurement.
  2. If the flag reappears, contact Roche Service.
- TEST
  1. Check sample for bubbles and repeat measurement.
  2. If the flag reappears, contact Roche Service.

Attributes Priority: 4

Group: CAL, CNTL, TEST

HIGH ABS

Meaning High absorbance.

The measured absorbance is greater than 2.0 A.

Recommended action

- CAL
  - Repeat with fresh calibrator.
- CNTL
  - If a single control is flagged, rerun with a fresh control.
  - If more than one control is flagged, perform a calibration.
- TEST
  - If a single sample is flagged, rerun with dilution.
  - If the problem persists, replace the cassette.

Attributes Priority: 1

Group: CAL, CNTL, TEST

HIGH ACT

Meaning High activity.

The Absorbance change during measurement exceeds the accepted limit, i.e. the reaction has taken off too fast. Possibility of substrate exhaustion.

Recommended action

- CAL
  1. Check reaction curve in Rate Info
  2. Check if correct calibrators placed on the calibrator rack.
  3. Repeat with fresh calibrators.
- CNTL
  1. Check reaction curve in Rate Info.
  2. Check control. Repeat with fresh control.
- TEST
  1. Check reaction curve in Rate Info.
  2. Rerun with dilution.

Attributes Priority: 17

Group: CAL, CNTL, TEST

HIGH BKG

Meaning High background noise.

For an FP measurement, there is an unacceptable level of background noise.

Recommended action

- CAL
  - Repeat with fresh calibrators
- CNTL
  1. Repeat with fresh controls.
  2. If the flag reappears, check that no fluorescence comes from the sample/control.
- TEST
  1. If single sample flagged, rerun with dilution.
  2. If the flag reappears, Check that no fluorescence comes from the sample/control.

     For some tests, you need to dilute the sample with zero calibrators.

Attributes Priority: 22

Group: CAL, CNTL, TEST

ISE UNSTAB

👁 *"ISE UNSTAB" on page F-44*

<KIN READ

Meaning Not enough kinetic readings.

Insufficient absorbance readings were found in the linear part of the reaction to be able to calculate a rate.

Not enough readings in kinetic range for calc mode Kinetic or Kinsearch

Recommended action

- CAL
  1. Check Rate info - reaction plot.
  2. Repeat with fresh calibrator.
  3. If little reaction occurs, replace cassette.
- CNTL
  1. Check Rate info - reaction plot.
  2. Repeat with fresh control.
  3. If little reaction occurs, replace cassette.
- TEST
  1. Check Rate info - reaction plot.
  2. Repeat with dilution if necessary.
  3. If little reaction occurs, replace cassette.

Attributes

Priority: 21

Group: CAL, CNTL, TEST

LOW ACT

Meaning

Low activity.

The absorbance change during the measurement is lower than the defined limit.

Recommended action

- CAL
  1. Check reaction curve in Rate Info.
  2. Check if correct calibrator was used.
  3. Repeat with fresh calibrators.
- CNTL
  1. Check reaction curve in Rate Info.
  2. Repeat with fresh control.
- TEST
  1. Check reaction curve in Rate Info.
  2. If the flag is for one sample: Check the sample tube or cup to ensure there is sufficient sample and that there are no bubbles, foam, or fibrin clots which could interfere with normal pipetting.
  3. If the flag is displayed for multiple samples for the same test: Check the reagent pipetting system for clogged or bent needles and ensure the currently used reagent cassette (with status in use) is in place and contains sufficient reagent.

Attributes

Priority: 18

Group: CAL, CNTL, TEST

<LOW LIM

Meaning

Less than lower limit.

For a limit control, the result is lower than the defined lower limit.

Recommended action

1. Check that the correct control material has been used.
2. Rerun with fresh control.
3. If the flag reappears, check calibration, cassette expiry and reaction curve

Attributes

Priority: 55

Group: CNTL

LOW SIGNAL

Meaning

Low signal.

For an FP measurement, a parallel or perpendicular intensity measurement was too low.

Recommended action

1. Repeat with fresh calibrators and SDRII diluent.
2. If the flag reappears, use new cassette.
3. If the flag reappears, contact Roche Service.

Attributes

Priority: 6

Group: CAL, CNTL, TEST

NO FLUID

“NO FLUID” on page F-45

NO ISECAL

“NO ISECAL” on page F-45

NON LINEAR

Meaning

Non-linear.

The first and last parts of the reaction curve have different slopes.

Recommended action

- CAL
  1. Check reaction plot.
  2. Repeat with fresh calibrator.
- CNTL
  1. Check reaction plot.
  2. Repeat with fresh control.
- TEST
  1. Check reaction plot.
  2. Rerun with dilution or concentration if necessary.

Attributes

Priority: 20

Group: CAL, CNTL, TEST

NON MONO

Meaning

Curve not monotonic.

No calibration curve could be calculated because the rates of the calibrators were non-monotonic.

Recommended action

1. Check the detail of the calibration.
2. If the calibrators were incorrectly positioned, replace the calibrators correctly and rerun the calibration.

Attributes

Priority: 25

Group: CAL

OUTLIERS

Meaning

Outliers.

For an FP measurement, too many outliers occurred in the parallel or perpendicular intensity measurements.

Air bubbles in the sample or electronic noise may be the cause.

Recommended action

1. Repeat with calibrators free of bubbles.
2. If the flag reappears, contact Roche Service.

Attributes

Priority: 3

Group: CAL, CNTL, TEST

OUT OF RNG

For ISE calibration, see

👁 *"OUT OF RNG (ISE)" on page F-46*

Meaning

Out of range.

Calibration curve or slope does not fall within programmed range.

Recommended action

1. Check calibration curve.
2. Repeat with fresh calibrators.
3. If the calibrators were incorrectly positioned, replace the calibrators correctly and repeat the calibration.
4. If flag reoccurs, replace cassette.

Attributes

Priority: 26

Group: CAL

p

Meaning

Result calculated using a postponed calibration which has been accepted.

Note: Postponing a calibration may lead to erroneous results.

Recommended actions

1. Review results.
2. Perform calibration if necessary.

Attributes

Priority: 35

Group: CNTL, RAT, TEST

P

Meaning

Result calculated using a postponed calibration which has not been accepted.

Note: Postponing a calibration may lead to erroneous results.

Recommended actions

1. Check all results carefully.
2. Perform calibration if necessary.

Attributes

Priority: 34

Group: CNTL, RAT, TEST

POL ERR

Meaning

Polarization error.

For an FP measurement the perpendicular measurement was higher than the parallel measurement.

Recommended action

1. Repeat the measurement.
2. If the flag reappears, contact Roche Service.

Attributes

Priority: 5

Group: CAL, CNTL, TEST

POS (value)

Meaning

Positive.

The sample result is greater than or equal to the cutoff value. (For semi-quantitative tests only.)

Recommended action

No action required.

Attributes

Priority: 66

Group: TEST

POSITIVE

Meaning

Positive.

The sample result is greater than or equal to the cutoff value. (For qualitative tests only.)

Recommended action

No action required.

Attributes

Priority: 67

Group: TEST

q

Meaning

The sample result is associated with an erroneous or corrected quality control result. The quality control has been accepted.

Recommended action

1. Repeat the quality control measurement in order to obtain an unflagged control result.
2. Repeat the sample if necessary.

Attributes

Priority: 37

Group: RAT, TEST

Q

Meaning

The sample result is associated with an erroneous or corrected quality control result. The quality control has not been accepted.

Recommended action

1. Repeat the quality control measurement in order to obtain an unflagged control result.
2. Repeat the sample if necessary.

Attributes

Priority: 36

Group: RAT, TEST

r

Meaning

Erroneous result.

The result is either erroneous or has been corrected (recalculated) and the result has been accepted.

One or more of the replicates either is erroneous or has been corrected (recalculated) and the result has been accepted.

Recommended action

- CAL
    - Repeat calibration after taking the appropriate action for the associated flag(s).
- CNTL
    1. Check control performance.
    2. Repeat control after taking the appropriate action for the associated flag(s).
- RAT
    - Repeat calibration and tests after taking the appropriate action for the associated flag(s).
- TEST
    - Repeat calibration and test after taking the appropriate action for the associated flag(s).

Attributes

Priority: 39

Group: CAL, CNTL, RAT, TEST

R

Meaning

Erroneous result.

- CAL, CNTL, TEST

  The result is either erroneous or has been corrected (recalculated) and the result has been accepted.
- RAT

  Result calculated using erroneous sample results which have not been accepted.

Recommended action

- CAL
    1. Check calibrator's reaction curve to establish the cause of the deviation.
    2. Repeat calibration with fresh calibrators.
- CNTL
    - Repeat test with fresh control.

- RAT
  1. Review controls.
  2. Repeat calibration.
  3. Repeat sample if necessary.
- TEST
  1. Check reaction curve to establish the cause of the deviation.
  2. Repeat test.

Attributes Priority: 38

Group: CAL, CNTL, RAT, TEST

R 1(2s)

Meaning Westgard rule 1 violated.

One quality control result deviated from the assigned mean (in either direction) by more than 2 standard deviations.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, cassette expiry and reaction curve.

Attributes Priority: 44

Group: CNTL

R 1(3s)

Meaning Westgard rule 2 violated.

One quality control result deviated from the assigned mean (in either direction) by more than 3 standard deviations.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, cassette expiry and reaction curve.

Attributes Priority: 45

Group: CNTL

R 2(2s)

Meaning Westgard rule 3 violated.

Two consecutive quality control results deviate from the assigned mean (in the same direction) by more than 2 standard deviations.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, cassette expiry and reaction curve.

Attributes Priority: 46

Group: CNTL

R (4s)

Meaning	Westgard rule 4 violated. The difference between two consecutive quality control results is greater than 4 standard deviations.
Recommended action	**1** Repeat with fresh control. **2** Check that the correct control material has been used. **3** If the flag reappears, check calibration, cassette expiry and reaction curve.
Attributes	Priority: 47 Group: CNTL

R 4(1s)

Meaning	Westgard rule 5 violated. Four consecutive quality control results deviate from the assigned mean by more than 1 standard deviation in the same direction.
Recommended action	**1** Repeat with fresh control. **2** Check that the correct control material has been used. **3** If the flag reappears, check calibration, cassette expiry and reaction curve.
Attributes	Priority: 48 Group: CNTL

R7 ↓ Drift

Meaning	Precision control rule violated. There were 7 consecutive decreasing quality control results.
Recommended action	**1** Repeat with fresh control. **2** Check that the correct control material has been used. **3** If the flag reappears, check calibration, cassette expiry and reaction curve. **Tip** Check regularly that all Service actions were performed.
Attributes	Priority: 49 Group: CNTL

R7 ↑ Drift

Meaning	Precision control rule violated. There were 7 consecutive increasing quality control results.
Recommended action	**1** Repeat with fresh control. **2** Check that the correct control material has been used. **3** If the flag reappears, check calibration, cassette expiry and reaction curve.

Tip

Check regularly that all Service actions were performed.

Attributes Priority: 50

Group: CNTL

R 7x

Meaning Precision control rule violated.

There were 7 consecutive quality control results falling on the same side of the assigned mean.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, cassette expiry and reaction curve.

Attributes Priority: 51

Group: CNTL

R 10x

Meaning Westgard rule 6 violated.

There were 10 consecutive quality control results falling on the same side of the assigned mean.

Recommended action

1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, cassette expiry and reaction curve.

Attributes Priority: 52

Group: CNTL

<REAG RNG

Meaning Less than reagent range.

The Absorbance value of the lowest calibrator is below the lower defined range

Recommended action

1. Check the calibration curve and cassette expiry.
2. Repeat with fresh lowest calibrator.
3. If the flag reappears, replace cassette (the reagent may be contaminated).

Attributes Priority: 14

Group: CAL

>REAG RNG

Meaning Greater than reagent range.

The absorbance value of the lowest calibrator is above the upper defined range.

Recommended action

1. Check the calibration curve and cassette expiry.
2. Repeat with fresh lowest calibrator.

3 If the flag reappears, replace cassette (the reagent may be contaminated).

Attributes

Priority: 15

Group: CAL

>REPL DEV

Meaning

Greater than replicate deviation.

Deviation between replicates exceed programmed limit. One or more replicates are erroneous.

Recommended action

1 Check the calibrators for air bubbles and repeat the calibration.

2 If the flag reappears, repeat with fresh calibrators.

Attributes

Priority: 23

Group: CAL

<RR (value)

Meaning

Less than reference range.

The result is lower than the low reference range limit.

Recommended action

No action required.

Attributes

Priority: 60

Group: RAT, TEST

>RR (value)

Meaning

Greater than reference range.

The sample result is higher than the high reference range limit.

Recommended action

No action required.

Attributes

Priority: 61

Group: RAT, TEST

SEG FLUID

👁 *“SEG FLUID” on page F-46*

SEG ISECAL

👁 *“SEG ISECAL” on page F-47*

SOL 1 F DEV

👁 *“SOL 1 F DEV” on page F-47*

>STD DEV

Meaning

Greater than standard deviation.

A point in the calibration fell outside the defined limits.

Recommended action

1. Check calibration curve.
2. Repeat with fresh calibrators.
3. If the calibrators were incorrectly positioned, replace the calibrators correctly.

Attributes

Priority: 27

Group: CAL

<TEST RNG

Meaning

Less than test range.

The result is lower than the lowest limit for the test.

Recommended action

- CAL
  - Repeat calibration.
- CNTL
  - Repeat with fresh controls.
- TEST
  - Rerun the sample with postconcentration if a sample predilution factor is defined for this application.

Attributes

Priority: 30

Group: CAL, CNTL, TEST

>TEST RNG

Meaning

Greater than test range.

The result is higher than the upper limit for the test.

Recommended action

- CAL
  - Repeat calibration.
- CNTL
  - Repeat with fresh controls.
- TEST
  - Rerun the sample with postdilution. With TDM tests, use manual dilution (diluent or zero calibrator).
  - If the sample has already been postdiluted, rerun the sample with a higher postdilution factor

Attributes

Priority: 31

Group: CAL, CNTL, TEST

>UP LIM

Meaning

Greater than upper limit.

For a limit control, the result is higher than the defined upper limit.

Recommended action

1. Rerun with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check calibration, cassette expiry and reaction curve.

Attributes

Priority: 54

Group: CNTL

>

Meaning

- CAL and CNTL: Repeat

  The result was generated from a repeat.

- TEST: Rerun

  The result was generated from a rerun.

Recommended action

No action required.

Attributes

Priority: 43

Group: CAL, CNTL, TEST

∨

Meaning

Diluted.

The result was generated using a diluted sample and the dilution factor was automatically applied to the result calculation.

Recommended action

No action required.

Attributes

Priority: 41

Group: CNTL, TEST

^

Meaning

Concentrated.

The result was generated using a concentrated sample and the concentration was automatically applied to the result calculation. Only applicable to tests defined to use predilution.

Recommended action

No action required.

Attributes

Priority: 42

Group: CNTL, TEST

Service D

Part D describes the routine maintenance tasks, called service actions, that you must perform to keep the instrument running at maximum throughput. It describes how the system reacts to service actions when they are due and how to change service intervals, if necessary. It also provides step-by-step instructions on how to perform each service action, plus a few related tasks.

Service action software

Using the Service work area for preventative maintenance

Service actions are an essential part of your maintenance strategy. Completing service actions correctly and on time helps to ensure that your laboratory gets the maximum benefit from your instrument.

This chapter describes the Service work area and the procedures that are used to track and initiate service actions. When you perform a service action, a set of online instructions is displayed to show you how to clean or replace parts of the instrument.

In this chapter

Chapter **13**

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Warning

Important safety information
Read and understand the Roche safety precautions at the beginning of this manual and the hazard and precaution notes contained in this chapter. This information should be made available to all employees and kept for further reference.
Users must not perform any servicing except as explicitly described in this manual.

About service actions

You must perform a number of service actions to ensure that your instrument runs reliably.

Use the Service work area to track and perform service actions. When any service action is due, the Service icon on the navigation bar turns yellow. If the Service icon is red it means that the backup database service action is overdue.

Generally, the instrument must be in Standby when you are performing service actions. The ISE service actions Activate electrodes and Prime ISE calibrators are exceptions to this.

Chapter 18, "ISE service actions"

When are service actions due?

The due time for a service action is determined by the counters and timers that are maintained by the system. For example, with the default values, the Clean probes and splash guard service action is listed on the Due tab either

- after 3000 tests

or

- after 7 days.

The system uses the service interval (number of tests or number of days) that occurs soonest. Service intervals can be changed by your system supervisor. When the service action has been performed, the counters and timers are reset.

When are service actions nearly due?

The system defines service actions to be "nearly due" by using a percentage of the service interval. For example, using 90% for the "Service Action Due at" calculation, the Clean probes and splash guard service action is listed on the Due tab either

- after 2700 tests have been done (90% of 3000)

or

- after 6.3 days have passed (90% of 7).

The percentage can be changed by your system supervisor.

The Begin of Day tab lists only service actions that will be performed automatically at the next BOD.

Service work area overview

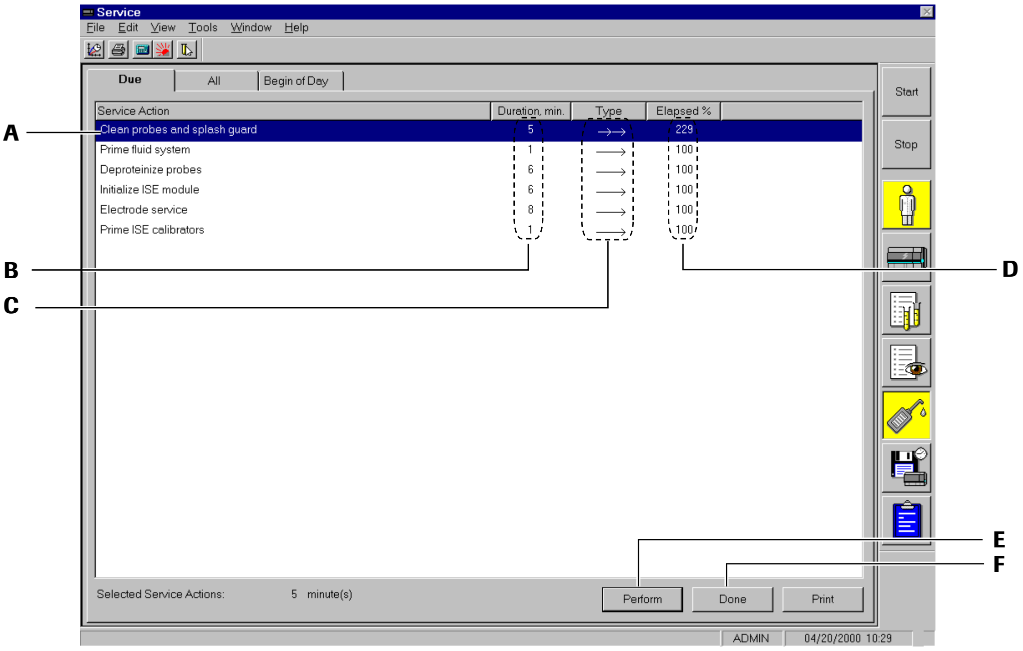
To access the Service work area, click the Service button on the navigation bar.

The Service work area has the following tabs:

Tab	Function
Due	This tab lists service actions that are nearly due, due and overdue.
All	This tab lists all the service actions.
Begin of Day	This tab lists service actions that are to be automatically performed at the Begin of Day.

Due tab

The Due tab lists all due, nearly due, and overdue service actions. It tells you how long the service action will take to perform and whether it is partially or fully automatic.



Service Action	Duration, min.	Type	Elapsed %
Clean probes and splash guard	5	→→	229
Prime fluid system	1	→	100
Deproteinize probes	6	→	100
Initialize ISE module	6	→	100
Electrode service	8	→	100
Prime ISE calibrators	1	→	100

Selected Service Actions: 5 minute(s)

A *Overdue items are highlighted when you click the Due tab. The items that are not highlighted are almost due.*

B *Shows the time it takes to perform the service action.*

C *➔➔ is a service action with user intervention.*
➔ is an automatic service action without user intervention.

D *Shows whether the service action is almost due (less then 100%), due (100%) or overdue (more than 100%).*

E *Click Perform to perform the highlighted service action. The dialog box that lists the instructions for performing the service action is displayed.*

F *Click Done if you do not intend to perform the service action but wish to reset the counters to zero. The service action is removed from the Due tab.*

Tips

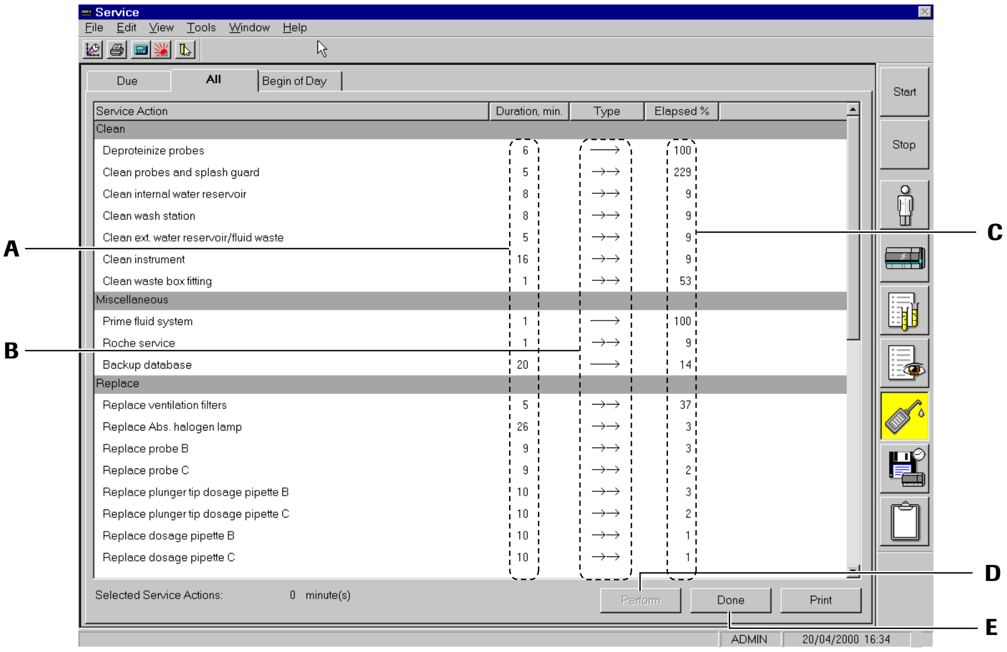
- Display the details for a particular service action by:
  - Double-clicking the item in the list.
  - Right-clicking the item, then choosing Detail.
- Choose View > Notes to see a list of user actions and service actions that have been performed. The paper clip indicates the presence of a Service note.

  “Service notes” on page D-13

- Press F1 to display Help for this tab.

All tab

The All tab lists all of the service actions. It tells you how long the service action will take to perform, whether it is partially or fully automatic, and whether it is due.



Service Action	Duration, min.	Type	Elapsed %
Clean			
Deproteinize probes	6	→	100
Clean probes and splash guard	5	→→	229
Clean internal water reservoir	8	→→	9
Clean wash station	8	→→	9
Clean ext. water reservoir/fluid waste	5	→→	9
Clean instrument	16	→→	9
Clean waste box fitting	1	→→	53
Miscellaneous			
Prime fluid system	1	→	100
Roche service	1	→→	9
Backup database	20	→	14
Replace			
Replace ventilation filters	5	→→	37
Replace Abs. halogen lamp	26	→→	3
Replace probe B	9	→→	3
Replace probe C	9	→→	2
Replace plunger tip dosage pipette B	10	→→	3
Replace plunger tip dosage pipette C	10	→→	2
Replace dosage pipette B	10	→→	1
Replace dosage pipette C	10	→→	1

Selected Service Actions: 0 minute(s)

ADMIN 20/04/2000 16:34

A *Shows the time it takes to perform the service action in minutes.*

B *➔➔ is a service action with user intervention.*
➔ is an automatic service action without user intervention.

C *Shows whether the service action is almost due (less then 100%), due (100%) or overdue (more than 100%).*

D *Click Perform to perform the highlighted service action. The dialog box that lists the instructions for performing the service action is displayed.*

E *Click Done if you do not intend to perform the service action but wish to reset the counters to zero. The service action is removed from the Due tab.*

Tips

- Display the details for a particular service action by:
  - Double-clicking the item in the list.
  - Right-clicking the item, then choosing Detail.
- Choose View > Notes to see a list of user actions and service actions that have been performed. The paper clip indicates the presence of a note.

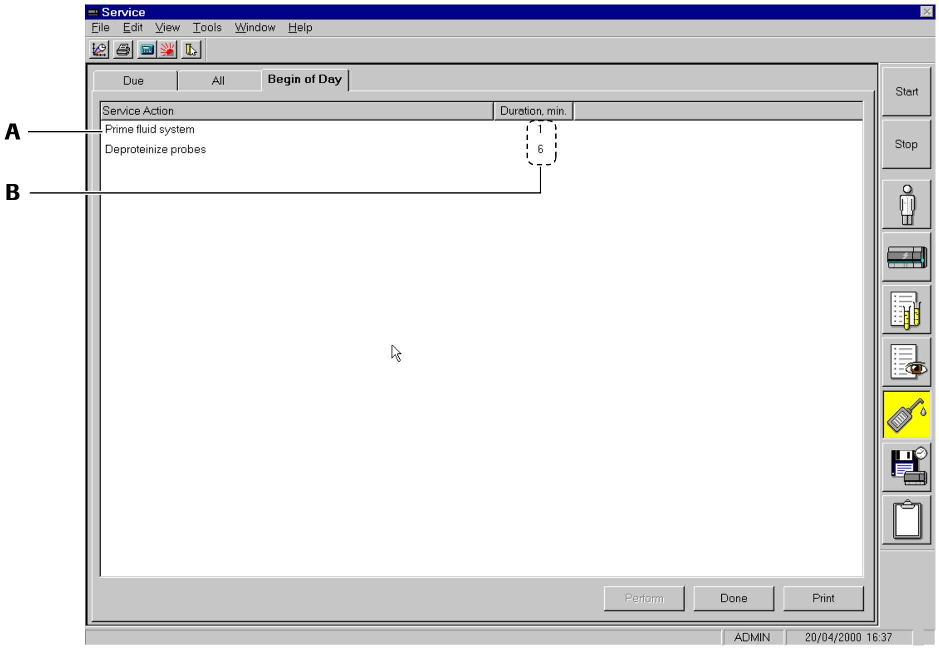
  "Service notes" on page D-13

- Press F1 to display Help for this tab.

Begin of Day tab

Your system can be set up to perform the following service actions at the Begin of Day:

Service action	When is the service action listed on the BOD tab?
Deproteinize probes	Listed on the Begin of Day tab after a specified number of tests or number of days (whichever is the shortest time) has occurred.
Prime fluid system	Listed on the Begin of Day tab after the instrument has been in Sleeping for a specified number of hours, or after a specified number of days (whichever is the shortest time).
Backup database	Listed on the Begin of Day tab after a specified number of tests or number of days (whichever is the shortest time) has occurred.
Initialize ISE module Activate electrodes Electrode service Prime ISE calibrators Clean ISE tower automatically Condition ISE tubing	ISE service actions: listed on the Begin of Day tab after a specified number of tests or number of days (whichever is the shortest time) has occurred.



Service Action	Duration, min.
Prime fluid system	1
Deproteinize probes	6

A *The service actions listed here will be performed at the next Begin of Day. They may be actions that are due at the next BOD, or actions that failed at the previous BOD.*

B *Shows the time it takes to perform the service action, in minutes.*

Tips

- You can perform the service actions displayed on the Begin of Day tab manually if necessary.
- Display the details for a particular service action by:

  - Double-clicking the item in the list.
  - Right-clicking the item, then choosing Detail.
- Choose View > Notes to see a list of user actions and service actions that been performed. The paper clip indicates the presence of a note.

  👁 *“Service notes” on page D-13*

- Press F1 to display Help for this tab.

Performing a service action

You can perform a service action from any of the three tabs in the Service work area. A series of instruction dialog boxes are displayed to guide you through the steps.

To perform a service action, the instrument must be in Standby status.

► To perform a service action

1 Click Service on the navigation bar.

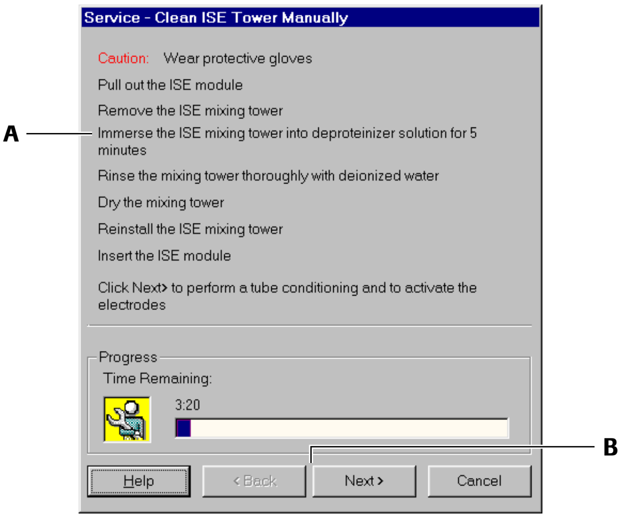
2 Do one of the following:

- Click the Due tab to display service actions that you must perform soon.
- Click the All tab to display all service actions whether they are due or not.
- Click the Begin of Day tab to display service actions that are performed automatically at the Begin of Day.

3 Select the service action to be performed and click Perform.

The service action dialog box is displayed. A typical example follows.

4 Follow the instructions listed on the dialog box.



Service - Clean ISE Tower Manually

Caution: Wear protective gloves

Pull out the ISE module

Remove the ISE mixing tower

Immerse the ISE mixing tower into deproteinizer solution for 5 minutes

Rinse the mixing tower thoroughly with deionized water

Dry the mixing tower

Reinstall the ISE mixing tower

Insert the ISE module

Click Next> to perform a tube conditioning and to activate the electrodes

A *Lists the instructions for you and the actions that the system performs.*

B *Click Next to go to the next set of steps.*
Click Finish when you have completed the service action.
Click Cancel to cancel the requested service action.
Click Help for more information on the selected action.

Tips

- For more detailed information about performing a service action:
  - Double-click the service action on the Due, All or Begin of Day tab.
  - Click Help on the dialog box.

- You may perform some service actions without using the Service action software. If you decide to do this, select the corresponding service action on the All tab, and click Done. The counters and timers will be reset to zero.

  Examples of the service actions where this is possible are replacing ventilation filters or cleaning the fluid waste reservoir.

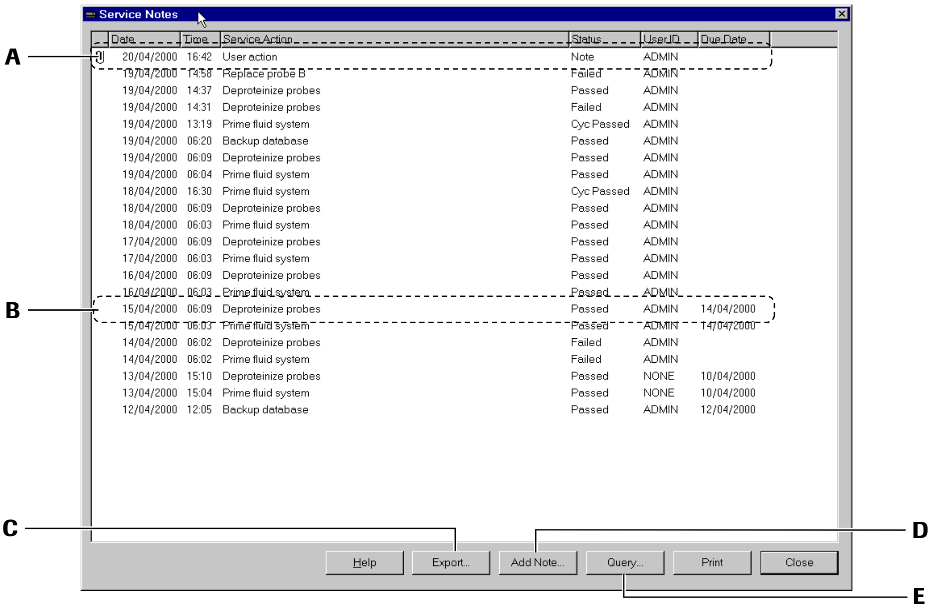
Caution

Important
Do not remove the internal water reservoir without using the Clean internal water reservoir service action.

Service notes

Service actions that have been performed are listed on the Service Notes dialog box. User actions are included in the list. A paper clip indicates that a note has been attached to the service action or that the note was added by a user.

To open the Service Notes dialog box, choose View > Notes on the Service work area.



	Date	Time	Service Action	Status	User ID	Due Date
📎	20/04/2000	16:42	User action	Note	ADMIN	
	19/04/2000	14:58	Replace probe B	Failed	ADMIN	
	19/04/2000	14:37	Deproteinize probes	Passed	ADMIN	
	19/04/2000	14:31	Deproteinize probes	Failed	ADMIN	
	19/04/2000	13:19	Prime fluid system	Cyc Passed	ADMIN	
	19/04/2000	06:20	Backup database	Passed	ADMIN	
	19/04/2000	06:09	Deproteinize probes	Passed	ADMIN	
	19/04/2000	06:04	Prime fluid system	Passed	ADMIN	
	18/04/2000	16:30	Prime fluid system	Cyc Passed	ADMIN	
	18/04/2000	06:09	Deproteinize probes	Passed	ADMIN	
	18/04/2000	06:03	Prime fluid system	Passed	ADMIN	
	17/04/2000	06:09	Deproteinize probes	Passed	ADMIN	
	17/04/2000	06:03	Prime fluid system	Passed	ADMIN	
	16/04/2000	06:09	Deproteinize probes	Passed	ADMIN	
	16/04/2000	06:03	Prime fluid system	Passed	ADMIN	
	15/04/2000	06:09	Deproteinize probes	Passed	ADMIN	14/04/2000
	15/04/2000	06:03	Prime fluid system	Passed	ADMIN	14/04/2000
	14/04/2000	06:02	Deproteinize probes	Failed	ADMIN	
	14/04/2000	06:02	Prime fluid system	Failed	ADMIN	
	13/04/2000	15:10	Deproteinize probes	Passed	NONE	10/04/2000
	13/04/2000	15:04	Prime fluid system	Passed	NONE	10/04/2000
	12/04/2000	12:05	Backup database	Passed	ADMIN	12/04/2000

A *User action not directly related to a particular service action. The paper clip indicates that the note was added by a user.*

B *Service action listed with the date and time it was performed, its status, and the user who performed it.*

C *Click to export notes.*

D *Click to add a service note to the selected service action. If no service action is selected, a user action is added to the list.*

E *Click this button to specify parameters that reduce the number of items displayed in the list.*

Tips

- The Due date column shows only Begin of Day service actions that were completed after the due date.
- Make the list more specific by clicking Query. The Service Notes Query dialog box is displayed. You can reduce the items in the list by specifying one or more of the following:
    - A type of service action
    - A time period
    - A user
- Check any service notes added by any user since the last work day. Double-click items with a paper clip next to them.
- Check any user actions, as these may contain information relevant to you.

Service action states

A service action has one of these states:

State	Meaning
Passed	The service action was completed successfully.
Aborted	The service action was canceled before completion.
Failed	The service action failed.
Manual	The service action was performed without the assistance of the service action software, and marked as performed by clicking Done on the All tab. This reset the counters to zero.
CycPassed	Some service actions can be performed while the instrument is running. Is a service action displayed in the Due list and the system is in running mode, a successfully passed service action gets the state “CycPassed”. This state is also listed in the Service Notes.
Note	A user action that may contain comments. You type additional comments into the note.

Adding service notes and user actions

You can attach a note to a service action, either when you complete the service action or later, from the Service Notes dialog box. You can also make your own entries on the Service Notes dialog box; these are listed as User Actions and are not associated with a service action.

► To add a service note

1 Click Service on the navigation bar.

2 Choose View > Notes.

The Service Notes dialog box is displayed.

3 Select the service action to which you want to add the note.

4 Click Add Note.

5 Type your comments in the Service - Add Note dialog box.

6 Click OK.

► To add a user action

1 Click Service on the navigation bar.

2 Choose View > Notes.

The Service Notes dialog box is displayed.

3 Make sure that no service action is selected (highlighted).

4 Click Add Note.

5 Type your comments in the Service - Add Note dialog box.

6 Click OK.

Tip

To deselect a selected service action, press and hold down the Ctrl key, then click the selected service action.

Counters and timers

To keep track of the work that the instrument does, the system maintains a set of counters and timers. These are used to determine when the different service actions become due. The Service work area tells you not only which service actions are due, but also when service actions are about to become due.

You can define both counters and timers for a service action. The system then uses whichever limit is reached first.

Performing a service action resets the counter and timer for that service action to zero.

An example of a counter

The system holds the following counters:

- The number of tests performed.
- A limit for the number of tests that a probe (for example) can do before it must be cleaned.

The service action becomes due when the number of tests performed reaches the limit.

An example of a timer

The system holds the following timers:

- The number of days that have passed since a service action was last performed.
- A limit for the number of days that can pass before a probe (for example) must be cleaned.

Counters, timers and due time

The system defines service actions to be due by using a percentage of the service interval. The permissible percentage range lies between 80% and 100%, and can be changed by your system supervisor. (Select View > Counters in the Service work area, click the Service Intervals tab, and type the value in the Service Action Due at box.)

To change the percentage, you must have user access level 6. (Configuration / General / User Level)

Once a counter or timer reaches the defined percentage of the service interval, the service action is displayed in the Due tab of the Service work area.

Service Counters dialog box

The Service Counters dialog box displays information about the counters and timers associated with service actions.

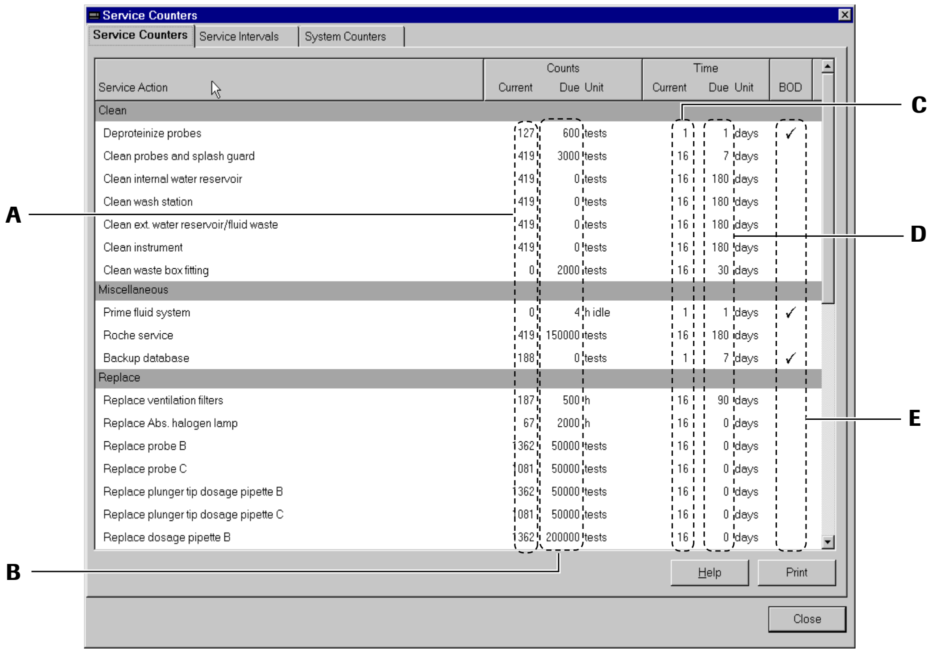
Choose View > Counters on the Service work area to open the Service Counters dialog box. There are three tabs:

- Service Counters
- Service Intervals
- System Counters

Service Counters tab

The Service Counters tab lists all the service actions with the counters and timers for each. The current status of each counter and timer is displayed along with the value that must be reached for the service action to become due. The service actions that are performed automatically at the Begin of Day are also shown here.

Choose View > Counters > Service Counters on the Service work area, to open the Service Counters tab.



Service Action	Counts Current	Counts Due	Counts Unit	Time Current	Time Due	Time Unit	BOD
Clean							
Deproteinize probes	127	600	tests	1	1	days	✓
Clean probes and splash guard	419	3000	tests	16	7	days	
Clean internal water reservoir	419	0	tests	16	180	days	
Clean wash station	419	0	tests	16	180	days	
Clean ext. water reservoir/fluid waste	419	0	tests	16	180	days	
Clean instrument	419	0	tests	16	180	days	
Clean waste box fitting	0	2000	tests	16	30	days	
Miscellaneous							
Prime fluid system	0	4	h idle	1	1	days	✓
Roche service	419	150000	tests	16	180	days	
Backup database	188	0	tests	1	7	days	✓
Replace							
Replace ventilation filters	187	500	h	16	90	days	
Replace Abs. halogen lamp	67	2000	h	16	0	days	
Replace probe B	1362	50000	tests	16	0	days	
Replace probe C	1081	50000	tests	16	0	days	
Replace plunger tip dosage pipette B	1362	50000	tests	16	0	days	
Replace plunger tip dosage pipette C	1081	50000	tests	16	0	days	
Replace dosage pipette B	1362	200000	tests	16	0	days	

A *The current number of tests, hours, or hours idle that have occurred for a service action. When this number has increased to match the number in the Due column, the service action must be performed.*

B *The number of tests, hours, or hours idle that must occur before the service action is performed.*

C *The current number of days that have passed since the service action was last performed.*

D *The number of days that must pass before the service action is performed.*

E *The ✓ symbol shows which service actions are performed at the Begin of Day.*

Service Intervals tab

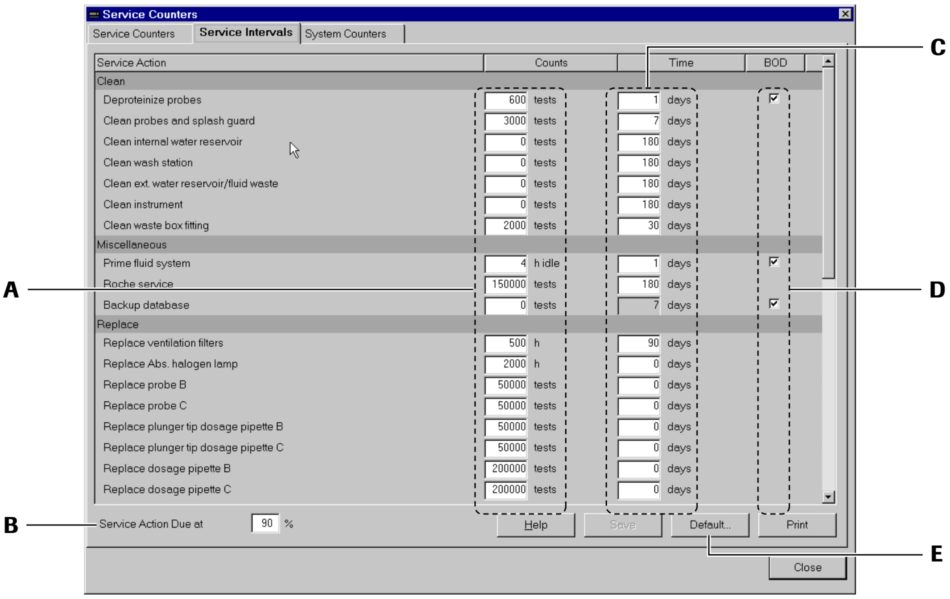
Service intervals are the values of the counters and timers that cause a service action to become due. You can change the values on this tab.

You normally must have user access level 6 to edit values on this tab.

Once a counter or timer reaches the defined percentage of the service interval, the service action is displayed in the Due tab of the Service work area. The permissible percentage range lies between 80% and 100%, and can be changed by your system supervisor. (Select View > Counters in the Service work area, click the Service Intervals tab, and type the value in the Service Action Due at box.)

To change the percentage, you must have user access level 6.

Choose View > Counters > Service Intervals on the Service work area, to open the Service Intervals tab.



Service Action	Counts	Time	BOD
Clean			
Deproteinize probes	600 tests	1 days	☑
Clean probes and splash guard	3000 tests	7 days	
Clean internal water reservoir	0 tests	180 days	
Clean wash station	0 tests	180 days	
Clean ext. water reservoir/fluid waste	0 tests	180 days	
Clean instrument	0 tests	180 days	
Clean waste box fitting	2000 tests	30 days	
Miscellaneous			
Prime fluid system	4 h idle	1 days	☑
Roche service	150000 tests	180 days	
Backup database	0 tests	7 days	☑
Replace			
Replace ventilation filters	500 h	90 days	
Replace Abs. halogen lamp	2000 h	0 days	
Replace probe B	50000 tests	0 days	
Replace probe C	50000 tests	0 days	
Replace plunger tip dosage pipette B	50000 tests	0 days	
Replace plunger tip dosage pipette C	50000 tests	0 days	
Replace dosage pipette B	200000 tests	0 days	
Replace dosage pipette C	200000 tests	0 days	

Service Action Due at 90 %

A *Type the number of tests, cuvettes, hours, or hours idle that must occur before the service action becomes due.*

B *Service actions are due when a percentage of the service interval is reached.*

C *Type the number of days that must pass before the service action becomes due.*

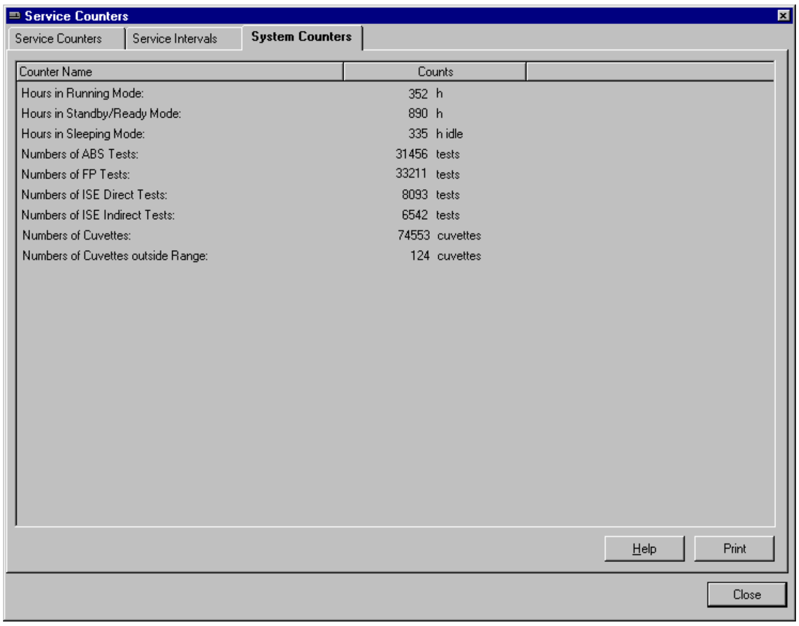
D *Select the check box if you want the service action to be performed automatically at the Begin of Day. The service action becomes due when either the counter or the timer threshold value is reached. When they are due, selected service actions appear on the Due tab on the Service work area.*

E *Use this button to reset intervals to the Roche defined default values. It can apply to a single selected service action or to all service actions.*

System Counters tab

The System Counters tab displays the internal counters maintained by the system. The counters are updated automatically and all other counters are derived from them. These counters are always maintained, even through software updates. You cannot change any values on this dialog box.

Choose View > Counters > System Counters on the Service work area, to open the System Counters tab.



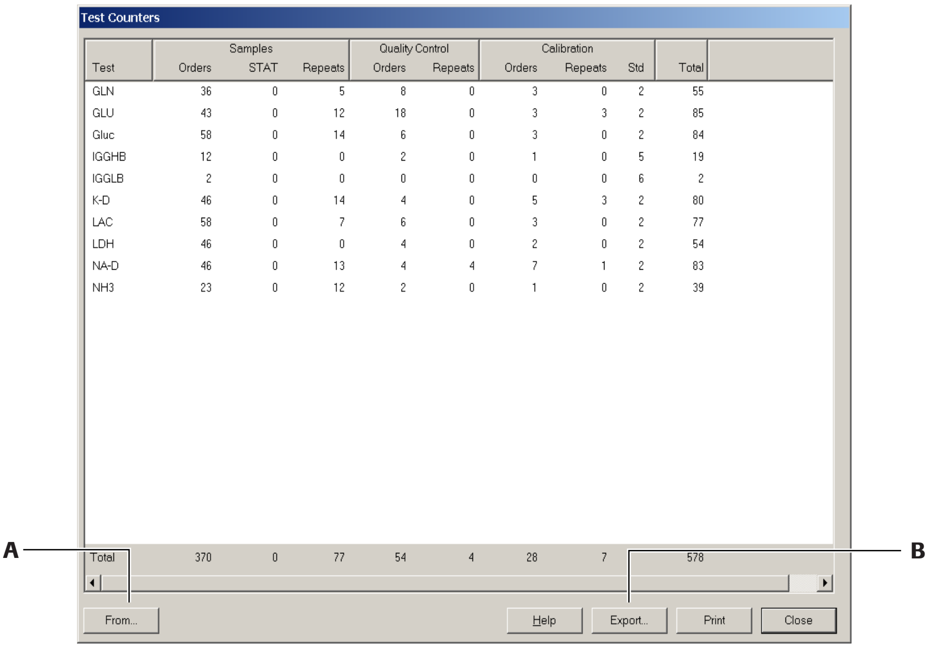
Counter Name	Counts	
Hours in Running Mode:	352 h	
Hours in Standby/Ready Mode:	890 h	
Hours in Sleeping Mode:	335 h idle	
Numbers of ABS Tests:	31456 tests	
Numbers of FP Tests:	33211 tests	
Numbers of ISE Direct Tests:	8093 tests	
Numbers of ISE Indirect Tests:	6542 tests	
Numbers of Cuvettes:	74553 cuvettes	
Numbers of Cuvettes outside Range:	124 cuvettes	

Test Counters dialog box

For each test defined on your system, the Service work area maintains counts for orders, repeats, and the total.

These counters are always maintained, even through software updates; however, if you delete a test definition from the instrument, the corresponding counters are also deleted.

To open the Test Counters dialog box, choose Tools > Test Counters on the Service work area.



	Samples			Quality Control		Calibration			
Test	Orders	STAT	Repeats	Orders	Repeats	Orders	Repeats	Std	Total
GLN	36	0	5	8	0	3	0	2	55
GLU	43	0	12	18	0	3	3	2	85
Gluc	58	0	14	6	0	3	0	2	84
IGGHB	12	0	0	2	0	1	0	5	19
IGGLB	2	0	0	0	0	0	0	6	2
K-D	46	0	14	4	0	5	3	2	80
LAC	58	0	7	6	0	3	0	2	77
LDH	46	0	0	4	0	2	0	2	54
NA-D	46	0	13	4	4	7	1	2	83
NH3	23	0	12	2	0	1	0	2	39
Total	370	0	77	54	4	28	7		578

A *Click this button to show the counts for the last n days, a specific date range, or a specific month.*

B *You can export the data in this table into a spreadsheet (independent of the Service work area).*

Tip

To calculate the counters of a specific day, click From and enter the same date in both the From and To boxes on the Test Counters Query dialog box.

Service actions

Scheduled tasks for preventative maintenance

This chapter provides step-by-step procedures to guide you through the non-ISE service actions that require manual intervention. It lists the potential hazards and precautions in each case. General maintenance procedures are also described.

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Danger

Before removing main cover disconnect mains plug from socket. Hazardous voltage is present on ISE power supply even if main switch is off. Danger of electric shock when touching power supply components.

Warning

Read and understand the Roche safety precautions at the beginning of this manual and the hazard and precaution notes contained in this chapter. This information should be made available to all employees and kept for further reference.
Users must not perform any servicing except as explicitly described in this manual.

Caution

Main front cover
Danger of injury due to closing main front cover. If the main front cover is not opened completely it might close unintentionally by itself.
Whenever you open the main front cover, be sure to open it as far as it will go.

For cleaning RD15 racks (sample racks), ISE rack and cassette racks, use active oxygen based mild cleaning solution.

Deproteinize probes

Overview	*This is an automatic service action that does not require manual intervention.* To maintain the efficiency of the instrument, you must clean and deproteinize the probes regularly to prevent the build up of contaminants. By default, Deproteinize probes is a Begin of Day action, but you can initiate it at any time from the Service work area.
Duration	6 minutes
Interval	Daily or after 600 tests
Tools and materials	• ISE deproteinizer on the ISE rack • Activator on the ISE rack
Hazards and precautions	None
Further information	For general information about performing a service action, see Chapter 13, “Service action software”

► To deproteinize probes

1. Select Deproteinize probes in the Service work area.
2. Click Perform.

   The Service Actions dialog box is displayed; follow the online instructions.
3. Wash pipes are filled with deproteinizer (automatic step).
4. Probes and sample loops are filled with deproteinizer (automatic step).
5. Probes are positioned inside the wash pipes (automatic step).
6. Probes are moved up and down (automatic step).
7. Prime fluid system is performed (automatic step).
8. Probes are activated (automatic step).
9. Prime fluid system is performed (automatic step).

Clean probes and splash guard

Overview You must clean the probes and splash guard regularly by hand to prevent any build up of deposits that may affect results.

The splash guard is a black plastic tray that prevents direct user access to the probes, thus protecting them from accidental damage. It also catches any drips of liquid on the outside of the probes, preventing contamination of other parts of the instrument.

Duration 5 minutes

Interval Weekly or after 3000 tests

Tools and materials

- 70% ethanol solution
- Protective gloves
- Paper tissues
- Soap

Hazards

- The sample area, analyzer module, ISE module, fluid waste, cuvette waste, and transfer head are potentially infectious.
- Reagents can cause burns, irritation, and poisoning through skin contact.

Precautions

- Wear protective gloves.
- Take care not to bend the probes.

Further information

- Double-click the service action in the Due, All, or Begin of Day tab
- Click Help in the dialog box
- For general information about performing a service action, see Chapter 13, “Service action software”

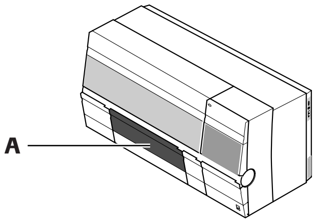
► **To clean probes and splash guard**

1 Select Clean probes and splash guard in the Service work area.

2 Click Perform.

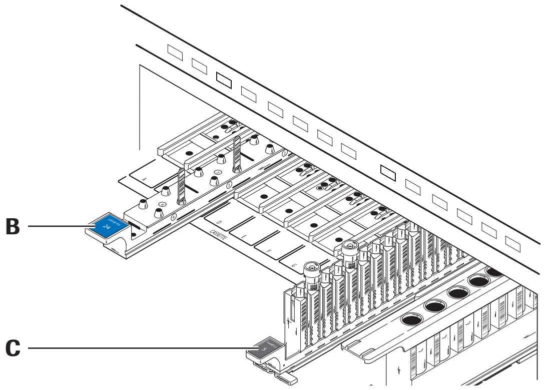
The Service Actions dialog box is displayed; follow the online instructions.

3 Open the rack access panel on the front of the instrument (A).



4 Remove all sample racks (C) and the ISE rack (D).

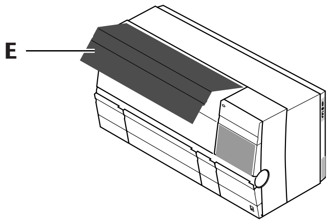
You do not have to remove the cassette racks (B).



5 Click Next.

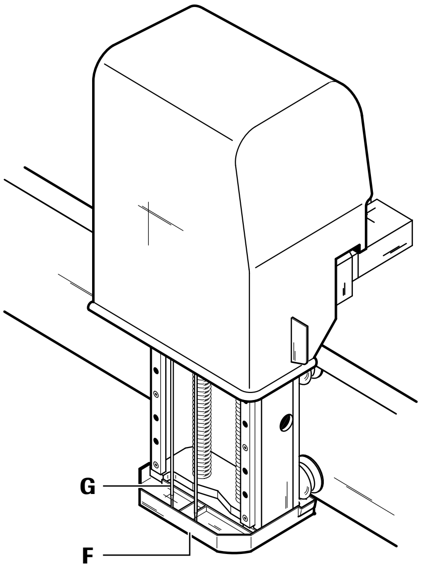
6 The transfer head is positioned in the sample area (automatic step).

7 Open the main front cover (E) to access the probes and splash guard.



8 Remove the splash guard (F).

Pull down the clip at the back of the splash guard to disengage it from the housing.



9 Clean both probes (G) with a tissue moistened with 70% ethanol.

Clean the probes from top to bottom.

10 Clean every part of the splash guard with soap and water.

11 Rinse and dry the splash guard.

12 Reinstall the splash guard.

13 Click Next.

14 The transfer system is initialized (automatic step).

15 Reinstall sample racks and the ISE rack.

16 Click Next.

17 Make any necessary notes and click Finish.

Clean internal water reservoir

Overview	You must clean the internal water reservoir to prevent the build up of contaminants which can affect the water quality, and therefore the quality of the results produced. At the same time, you must also replace the liquid filters, which filter out particulate matter from the water supply. Do not remove the internal water reservoir unless you are using the service action Clean internal water reservoir.
Duration	8 minutes
Interval	Once every six months
Tools and materials	• 2 new liquid filters • Protective gloves • Reagent grade, type 1 water • Paper tissues • 0.6% sodium hypochlorite solution
Hazards	• The sample area, analyzer module, ISE module, fluid waste, cuvette waste, and transfer head are potentially infectious. • Reagents can cause burns, irritation, and poisoning through skin contact.
Precautions	• Wear protective gloves.
Further information	• Double-click the service action in the Due, All, or Begin of Day tab. • Click Help in the dialog box. • For general information about performing a service action, see Chapter 13, "Service action software".

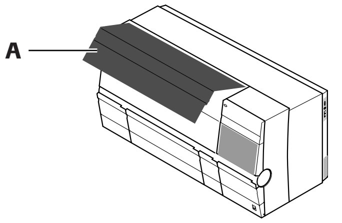
► To clean the internal water reservoir

1 Select Clean internal water reservoir in the Service work area.

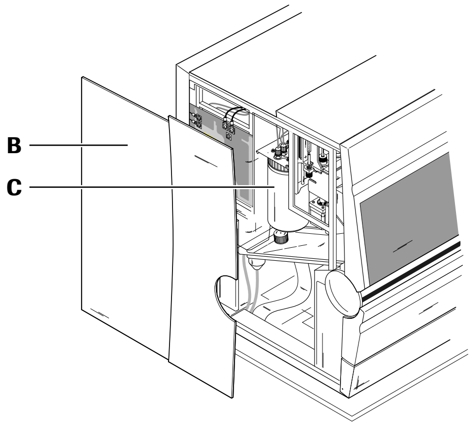
2 Click Perform.

The Service Actions dialog box is displayed; follow the online instructions.

3 Open the main front cover (A).

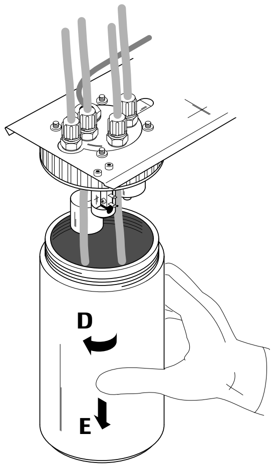


4 Remove the left side panel (B) to access the internal water reservoir (C).



5 Unscrew the internal water reservoir (D and E).

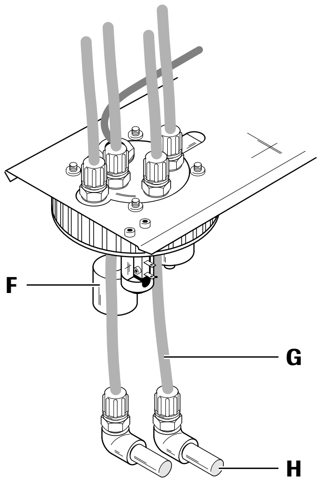
The reservoir may be full; take care not to spill any water.



6 Empty the reservoir and clean it with 0.6% sodium hypochlorite solution.

7 Rinse the reservoir thoroughly with reagent grade, type 1 water four times.

8 Clean the internal water reservoir level switch (F) and the suction pipes (G) using a tissue moistened with ethyl alcohol.



9 Rinse thoroughly with water.

10 Replace the liquid filters (H) at the end of the suction pipes.

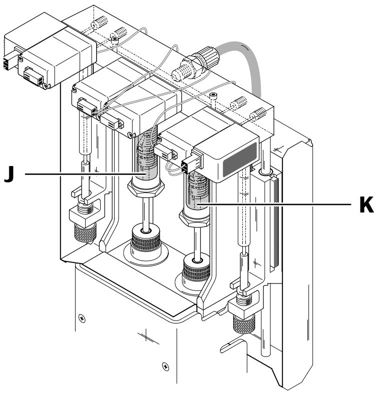
Wear clean protective gloves so that you do not contaminate the filters.

11 Reinstall the clean empty internal water reservoir.

12 Click Next.

13 The internal water reservoir is filled and the system is primed (automatic step).

14 Check the wash pipettes for air bubbles (J and K).



15 If necessary, perform another prime fluid system (until no air bubbles are visible).

👁 *"Prime the fluid system" on page D-46*

16 Reinstall the left side panel and close the main front cover.

17 Click Finish.

Clean wash station

Overview	You must clean the wash station and the inner part of the wash pipes to ensure that no foreign materials build up.
Duration	8 minutes
Interval	Every six months
Tools and materials	• Wash pipe seals • Paper tissues • Cotton swabs • Soap • Protective gloves • Tweezers
Hazards	• The sample area, analyzer module, ISE module, fluid waste, cuvette waste, and transfer head are potentially infectious. • Reagents can cause burns, irritation, and poisoning through skin contact.
Precautions	• Wear protective gloves.
Further information	• Double-click the service action in the Due, All, or Begin of Day tab. • Click Help in the dialog box. • For general information about performing a service action, see Chapter 13, “Service action software”.

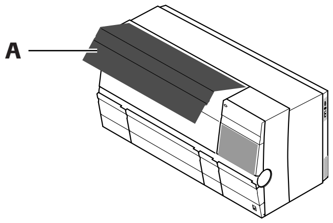
► To clean the wash station

1 Select Clean wash station in the Service work area.

2 Click Perform.

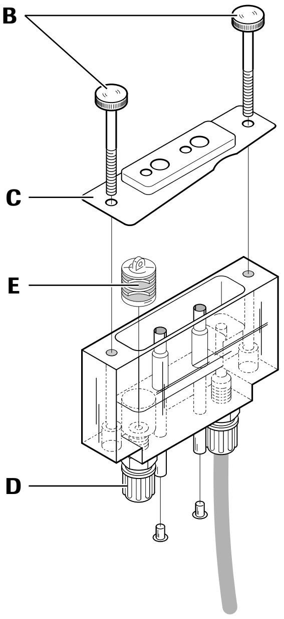
The Service Actions dialog box is displayed; follow the online instructions.

3 Open the main front cover (A).



4 Move the transfer head to one side so that you can access the wash station.

5 Remove the two screws on the wash station (B).



6 Remove the plastic cover (C).

Take note of the position of the cover so that you fit it correctly when reassembling the wash station.

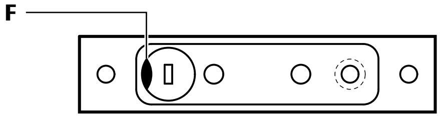
7 Lift the wash station, so that you can access the waste tubing connector (D).

8 Disconnect the waste tubing (not shown).

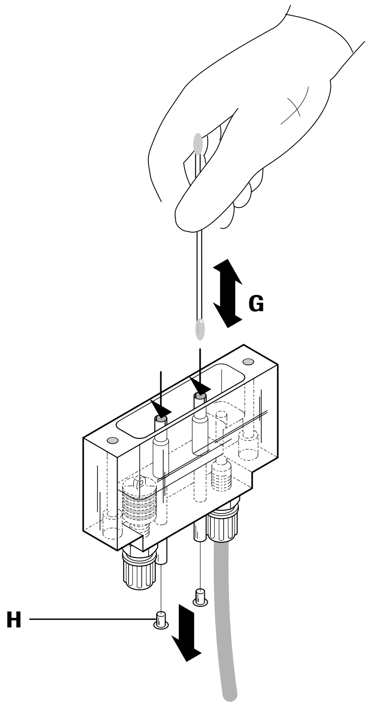
9 Use tweezers to remove the noise damper (E).

10 Rinse the noise damper with water.

11 Re-install the noise damper, making sure the notch faces outwards when you look at the wash station from above (F).



12 Clean the inner part of the wash pipes with cotton swabs (G).



13 Replace the wash pipe seals (H).

14 Rinse the wash station thoroughly using water.

15 Connect the waste tubing and reinstall the wash station.

16 When the wash station is in place, install the plastic cover (C).

The position of the cover must be with the wide end closest to you.

17 Click Next.

18 The transfer system is initialized (automatic step).

19 Click Finish.

Clean external water reservoir and fluid waste reservoir

Overview You must clean the external water reservoir and fluid waste reservoir to prevent the build up of contaminants which can affect the water quality and therefore the quality of the results produced.

This service action is not required if your instrument is directly connected to both a laboratory water supply and a laboratory fluid waste drain.

Duration 5 minutes

Interval Every three months

Tools and materials

- Liquid filters
- 0.6% sodium hypochlorite solution
- Clean beaker 1000 mL
- Reagent grade, type 1 water
- Paper tissues
- Protective gloves
- Ethyl alcohol

Hazards

- The sample area, analyzer module, ISE module, fluid waste, cuvette waste, and transfer head are potentially infectious.
- Reagents can cause burns, irritation, and poisoning through skin contact.

Precautions

- Wear protective gloves.

Further information

- Double-click the service action in the Due, All, or Begin of Day tab.
- Click Help in the dialog box.
- For general information about performing a service action, see Chapter 13, “Service action software”.

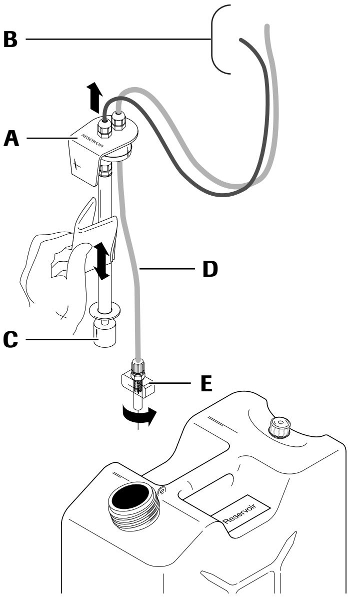
► **To clean the external water reservoir and the fluid waste reservoir**

1. Select Clean external water reservoir / fluid waste reservoir in the Service work area.
2. Click Perform.

   The Service Actions dialog box is displayed; follow the online instructions.
3. Pull out the tubing adapter (A) from the external water reservoir.

   Rest the adapter in a clean beaker to avoid contamination.

Do not disconnect the suction pipe or the level switch from the instrument (B).



4 Empty the external water reservoir.

5 Pour 1000 mL of 0.6% sodium hypochlorite solution into the external water reservoir and shake vigorously.

6 Repeat steps 4 and 5.

7 Rinse with reagent grade, type 1 water four times.

8 Clean the level switch (C) and suction pipe (D) with a tissue moistened with ethyl alcohol.

9 Replace the liquid filter (E) on the external water reservoir suction assembly.

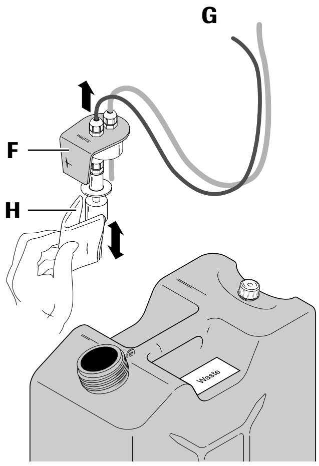
10 Fill the external water reservoir with reagent grade, type 1 water.

11 Reinstall the external water reservoir and insert the tubing adapter.

12 Pull out the tubing adapter (F) from the fluid waste reservoir.

Rest the adapter in a clean beaker to avoid contamination of the adapter and the work surfaces.

Do not disconnect the waste pipe or the level switch from the instrument (G).



13 Empty the fluid waste reservoir according to your local requirements for the disposal of potentially hazardous waste.

14 Pour 1000 mL of 0.6% sodium hypochlorite solution into the fluid waste reservoir and shake vigorously.

15 Repeat steps 13 and 14.

16 Clean the level switch (H) with a tissue moistened with ethyl alcohol.

17 Reinstall the fluid waste reservoir and insert the tubing adapter.

18 Click Finish.

Clean instrument

Overview	You must clean the instrument regularly to ensure that contaminants do not build up and affect the efficiency of the instrument as a measurement system. • Check the waste area for contamination and clean if necessary. • The surface of the initialization posts must be clean so that the analyzer can perform an error-free initialization of the transfer arms.
Duration	16 minutes
Interval	Every six months
Tools and materials	• 70% ethanol solution • Non-abrasive soap • Cuvette waste box tray • Paper tissues • Cuvette waste box • Hex driver (3 mm), unlock rack tool • Protective gloves
Hazards	• The sample area, analyzer module, ISE module, fluid waste, cuvette waste, and transfer head are potentially infectious. • Reagents can cause burns, irritation, and poisoning through skin contact.
Precautions	• Wear protective gloves.
Further information	• Double-click the service action in the Due, All, or Begin of Day tab. • Click Help in the dialog box. • For general information about performing a service action, see Chapter 13, “Service action software”.

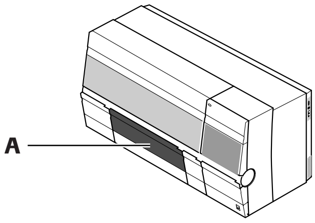
► **To clean the instrument**

1 Select Clean instrument in the Service work area.

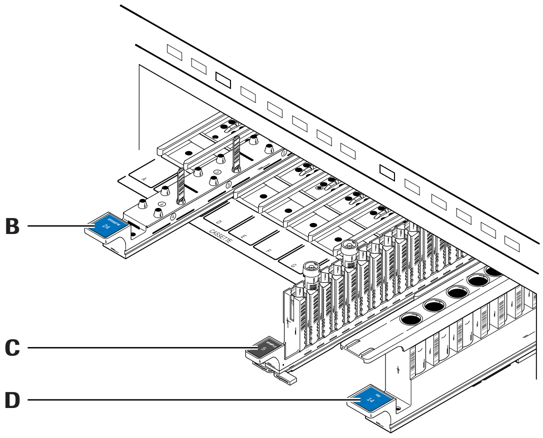
2 Click Perform.

The Service Actions dialog box is displayed; follow the online instructions.

3 Open the rack access panel on the front of the instrument (A).

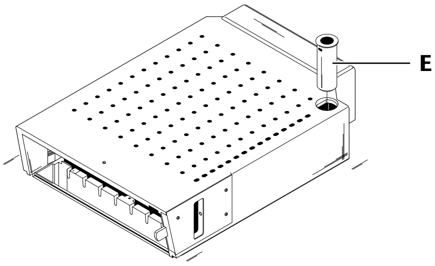


4 Remove cassette racks (B), sample racks (C), and the ISE rack (D).

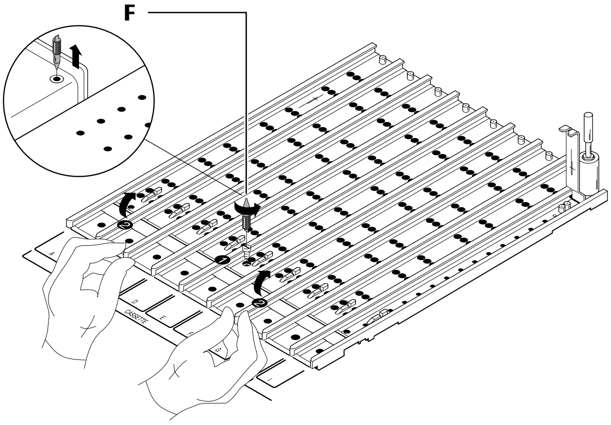


5 Open the main front cover.

6 Remove the cassette area initialization post insulator (E).

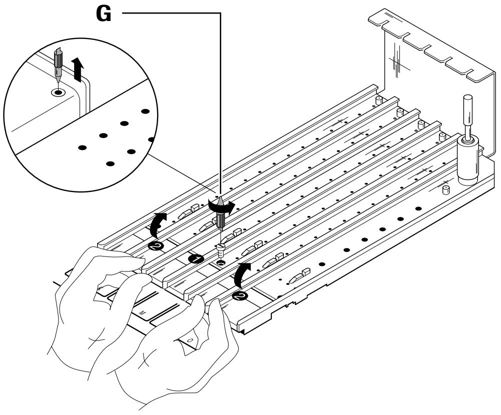


7 Use the unlock rack tool to remove the screw from the cassette rack platform (F).
Remove the platform.



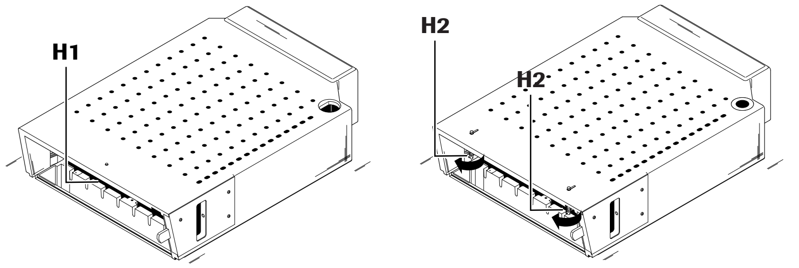
8 Use the unlock rack tool to remove the screw from the sample rack platform (G).

Remove the platform.



9 Remove the cooling box top:

a. Remove the screw (H1) under the front of the cooling box top, or turn the two spring loaded latches 180° (H2).



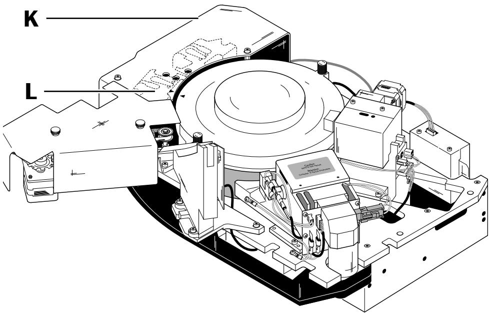
b. Pull the cooling box top forward, through the open rack access panel.

10 Clean both platforms with a tissue moistened with 70% ethanol.

11 Clean the cooling box base with a tissue moistened with 70% ethanol.

12 Reinstall both rack platforms.

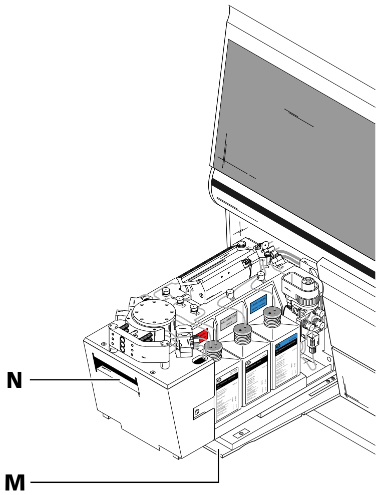
13 Remove the work station cover (K).



14 Clean the initialization surface of workstation B (L) with a tissue moistened with 70% ethanol.

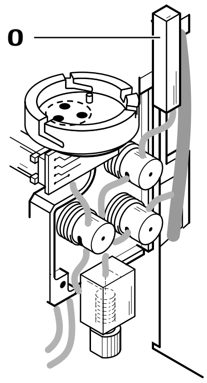
15 Clean both the inside and the outside of the work station cover with 70% ethanol. Reinstall the cover.

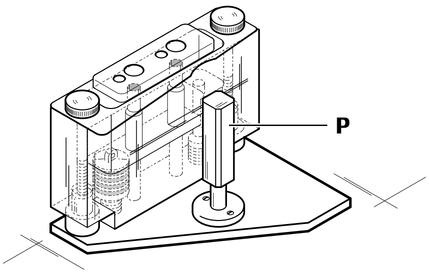
16 Open the ISE access panel (M) and pull out the ISE module using the handle (N).

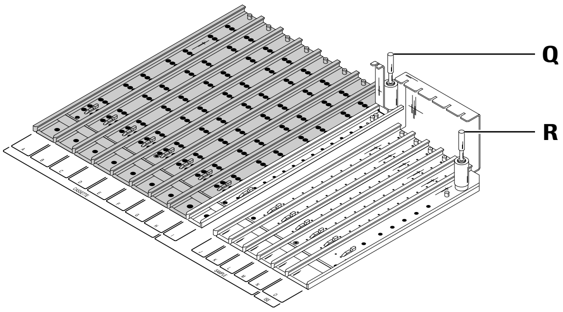


17 Use a tissue moistened with 70% ethanol to clean the initialization posts at the following locations:

- ISE module (O)
- Wash station (P)
- Cassette area (Q)
- Sample area (R)



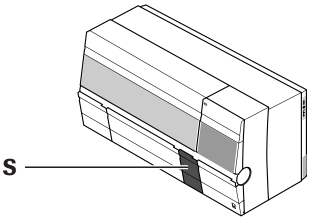




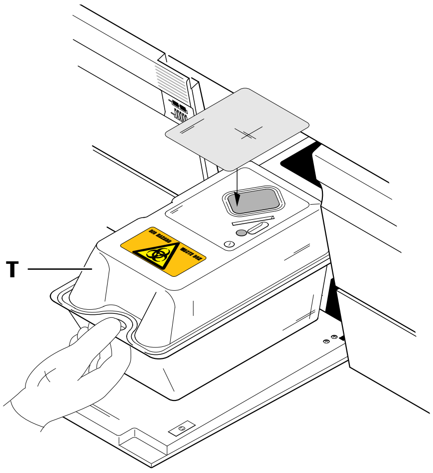
18 Reinstall the ISE module.

19 Clean the cooling box top and the cassette area initialization post insulator using 70% ethanol. Reinstall the cooling box top and the cassette area initialization post insulator.

20 Open the cuvette waste access panel (S).



21 Remove the cuvette waste box (T). Make sure shaking is not performed while you remove the box. Put a rectangular sticker over the holes on the top of the waste box and dispose of it according to your local requirements for the disposal of potentially hazardous waste.



22 Remove the cuvette waste box tray.

23 Clean the cuvette waste box tray with a tissue moistened with water.

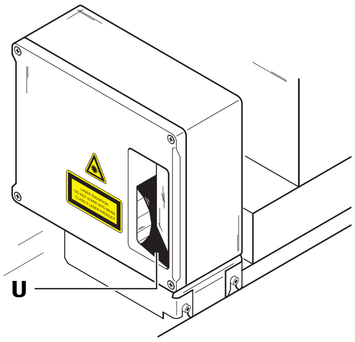
24 Clean the cuvette waste box housing using 70% ethanol.

25 Reinsert the cuvette waste box tray or replace it with a new one if needed.

26 Install a new cuvette waste box.

27 Clean all the access panels and the main front cover with soap and water.

28 Clean the barcode scanner window (U) with a dry tissue.



29 Reinsert all the racks.

30 Click Next.

31 The instrument is fully initialized (automatic step).

32 Click Finish.

Clean the waste box fitting

Overview Regular cleaning of the waste box fitting ensures proper functioning of the ISE module.

Duration 1 minute

Interval Every 30 days or after 2000 ISE tests are run.

Tools and materials

- Deionized water
- Protective gloves
- Paper tissue

Hazards

- The ISE module, including the tower, fluid waste, tubing, and electrodes, is potentially infectious.
- Sample material is potentially infectious.
- There is a danger of cauterization and poisoning through skin contact with the reagents.

Precautions

- Make sure you read all the warning labels on the cassettes.
- Use protective gloves to avoid direct contact with sample material.
- Remove any spillage of sample material immediately.

► To clean the waste box fitting

1. Select Clean waste box fitting in the Service work area.
2. Click Perform.

   The Service Actions dialog box is displayed. Follow the online instructions.
3. Remove the cuvette waste box. Make sure shaking is not performed while you remove the box.
4. Clean the Plexiglas protection of the waste box fitting with a paper tissue moistened with water.
5. Reinsert the cuvette waste box.
6. When all steps are complete, click Finish to reset the instrument service counters.

Further information

- Double-click the service action in the Due, All, or Begin of Day tab.
- Click Help in the dialog box.
- For general information about performing a service action, see Chapter 13, “Service action software”.

Clean and lubricate the rotor

Overview This action improves the cuvette positioning on the rotor. The positioning may affect the reproducibility of test results.

Duration 15 minutes

Interval When advised by Roche personnel or every 3 months.

Tools and materials

- Rotor Clean/Lube tool
  (This tool is included in the Accessories Kit supplied with the instrument.)

Hazards Due to sample spills, the rotor is potentially infectious.

This service action is not listed in the service work area of the system software.

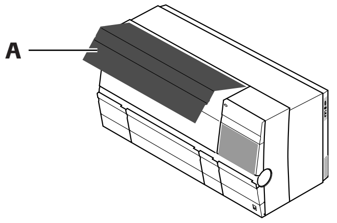
Precautions

- Wear protective gloves.

► To clean and lubricate the rotor

1 Perform a shutdown and switch off the instrument at the main switch.

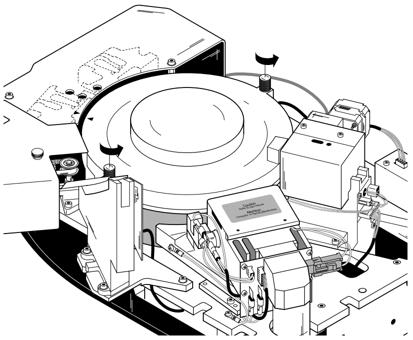
2 Open the main front cover (A) to access the transfer head.



3 Move the transfer head to the left to get access to the analyzer rotor cover.

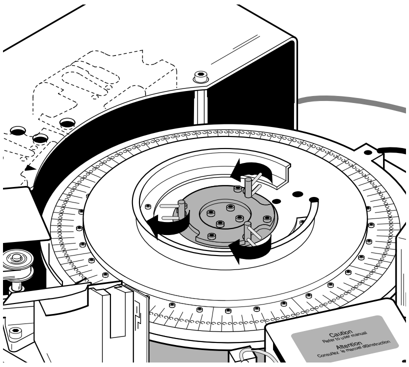
4 Unscrew the two screws (B) of the analyzer rotor cover.

5 Remove the analyzer rotor cover (C).

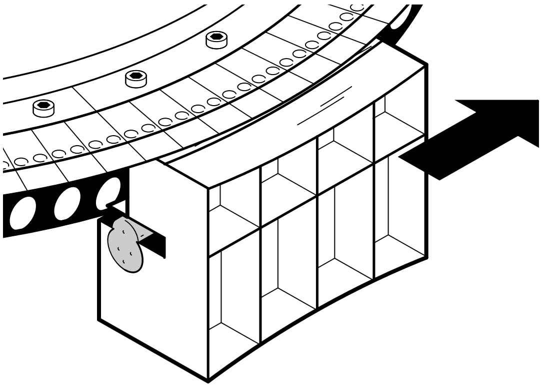


6 Lift & turn 90 degrees the three lever clips (D) on top of the rotor.

7 Carefully lift and remove the rotor.

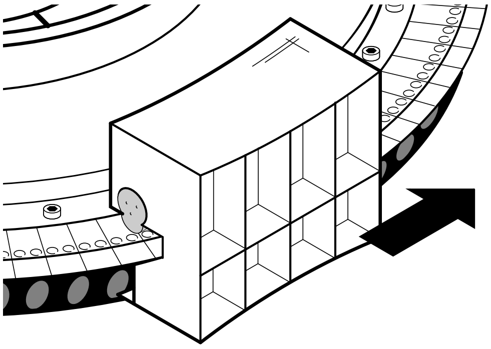


8 Mount the Rotor Clean/Lube tool on the rotor as shown in the following figure.



9 Slide back and forth the tool along the periphery of the rotor until the rotor is clean.

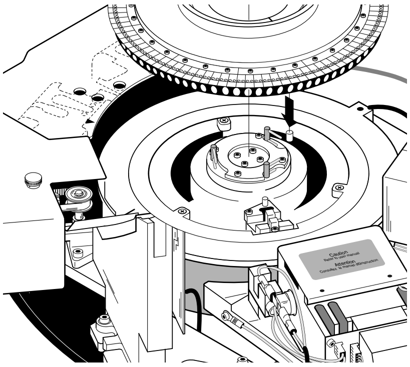
10 Remove the tool and mount it again upside down.



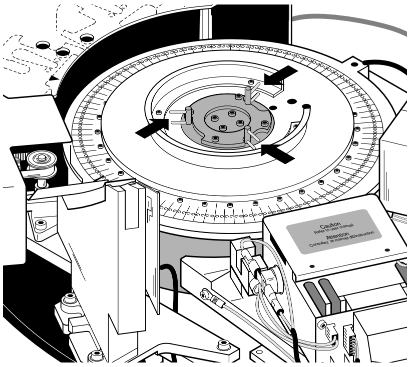
11 Slide back and forth the tool along the periphery of the rotor to lubricate the rotor balls.

12 Reinstall the rotor

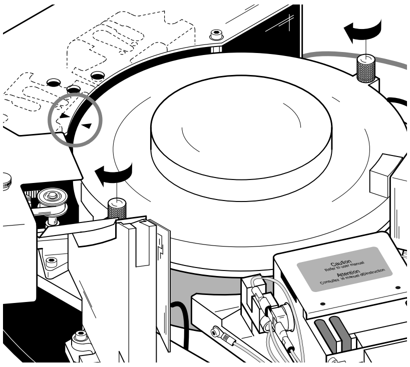
13 The positioning pin (E) must fit into the alignment hole (F) of the rotor.


Caution
Refer to user manual
Attention
Consultez le manuel d'instruction

14 Turn the three lever clips (G) 90 degrees to hold the rotor in position.


Caution
Refer to user manual
Attention
Consultez le manuel d'instruction

15 Reinstall the analyzer rotor cover. The white arrow (H) on the rotor cover must correspond with the white arrow on the workstation cover.


Caution
Refer to user manual
Attention
Consultez le manuel d'instruction

16 Restart the instrument at the main switch and wait until initialization is completed.

Prime the fluid system

Overview	*This is an automatic service action that does not require manual intervention.* Priming flushes the fluid system with water to ensure the paths in the fluid system (including pipettes, tubing, and probes) are filled with fluid and are free of air bubbles. If air bubbles are present in the fluid system, your test results will be inaccurate. Priming the fluid system is an automatic step in several service actions. You can also prime the fluid system automatically as a Begin of Day action, or at any time by selecting the action from the All tab in the Service work area.
Duration	2 minutes
Interval	Daily [BOD action] and if instrument is in Standby or Sleeping for more than 4 hours
Tools and materials	None
Hazards and precautions	None
Further information	• Double-click the service action in the Due, All, or Begin of Day tab. • Click Help in the dialog box. • For general information about performing a service action, see Chapter 13, “Service action software”.

► **To prime the fluid system**

1 Select Prime fluid system in the Service work area.

2 Click Perform.

The Service Actions dialog box is displayed; follow the online instructions.

3 Probes are positioned outside the wash pipes (automatic step).

4 Five wash cycles with system cleaner are performed (automatic step).

5 Probes are positioned inside the wash pipes (automatic step).

6 One wash cycle with system cleaner is performed (automatic step).

Roche service

Overview	The whole instrument must be regularly serviced by Roche Service engineers. This service action reminds you to contact Roche Service and arrange a visit.
Duration	Not applicable
Interval	Between 4 and 8 months or after 150,000 tests
Tools and materials	None
Further information	For general information about performing a service action, see Chapter 13, “Service action software”.

Backup database

Overview

This is an automatic service action that does not require manual intervention.

You must back up the database regularly to ensure the integrity of data on the system in the (unlikely) case of disk failure. If a backup becomes overdue, the background on the Service button in the navigation bar turns red.

Caution

Database backup must be performed in regular intervals otherwise the accumulated data will fill all available space on the hard disk and the system will be blocked.

Duration	5 minutes
Interval	Weekly
Tools and materials	None
Further information	For general information about performing a service action, see Chapter 13, “Service action software”.

Replace ventilation filter

Overview The ventilation filters remove particles from the air that is circulated through the instrument. There are two filters, one each for the analyzer, and the sample area.

You need to replace these filters according to the service action schedule in order to ensure that clean air can circulate.

Duration 5 minutes

Interval Every three months or after 500 hours in Running or Standby

Tools and materials
- Analyzer module ventilation filter
- Sample area ventilation filter

Hazards and precautions None

Further information For general information about performing a service action, see Chapter 13, “Service action software”.

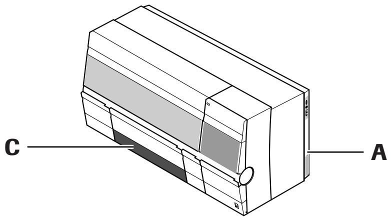
► To replace the ventilation filters

1 Select Replace ventilation filters in the Service work area.

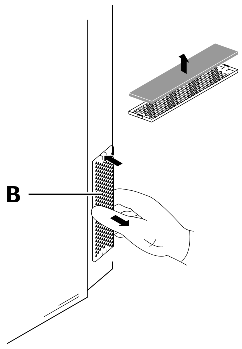
2 Click Perform.

The Service Actions dialog box is displayed; follow the online instructions.

3 Remove the filter covers at the right rear side of the instrument (A).



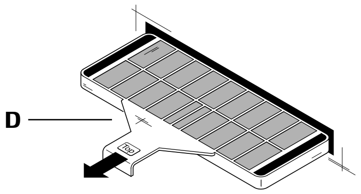
4 Replace the ventilation filter (B).

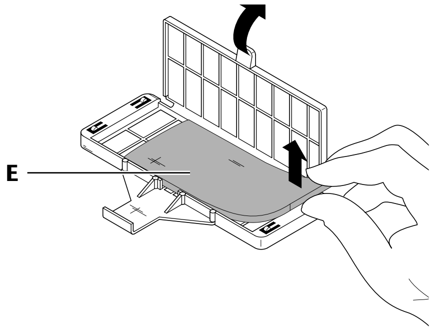


5 Reinstall the filter covers.

6 Remove the left bottom panel (C).

7 Pull out the sample area ventilation filter housing (D) and replace the filter (E).





8 Reinstall the filter housing.

9 Reinstall the left bottom panel.

10 Click Finish.

Replace Abs. halogen lamp

Overview The absorbance photometer uses a halogen lamp as its light source. It is essential that this lamp maintains a constant intensity in successive absorbance measurements. You must replace the lamp according to the service action schedule.

Duration 26 minutes

Interval After 800 hours in Running or Standby

Tools and materials
- Paper tissues
- Absorbance photometer halogen lamp

Hazards
- The lamp and surrounding components may be hot.

Precautions
- Do not touch the bulb surface. This reduces the life of the bulb and may affect the consistency of measurements made with the absorbance photometer.

Further information
- Double-click the service action in the Due, All, or Begin of Day tab.
- Click Help in the dialog box.
- For general information about performing a service action, see Chapter 13, “Service action software”.

► To replace the absorbance halogen lamp

1 Select Replace Abs. halogen lamp in the Service work area.

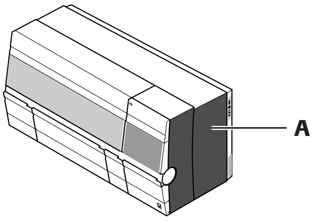
2 Click Perform.

The Service Actions dialog box is displayed; follow the online instructions.

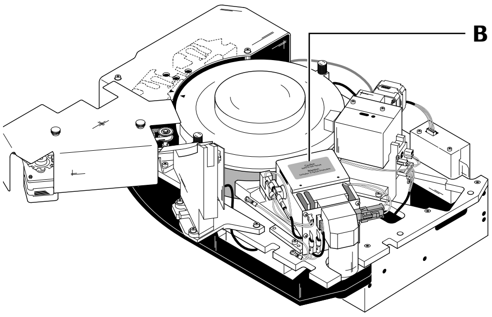
3 The absorbance halogen lamp is switched off (automatic step).

4 Wait 2-3 minutes for the lamp to cool.

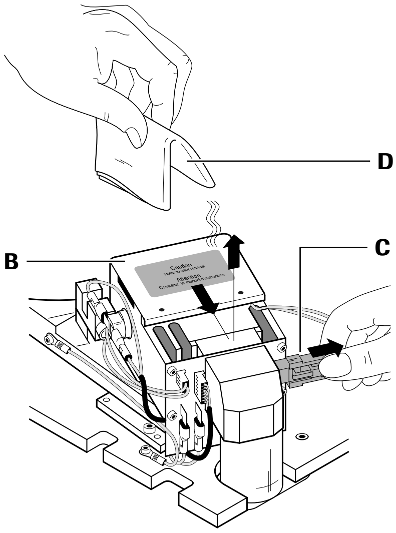
5 Remove the right side panel (A).



6 Remove the lamp cover (B).

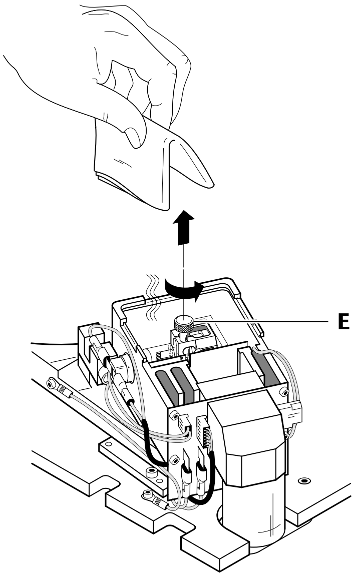


Use a dry cloth (D) to push the lamp cover (B) forward (towards the back of the instrument) about 1 cm and then lift it out.



7 Disconnect the lamp cable (C) and release the cable from its restraint.

8 Release the lamp by unscrewing the securing bolt (E) on the lamp holder.



9 Remove the whole lamp by lifting it with the bolt (E).

10 Replace the old lamp with a new one, taking care not to touch the lamp itself.

11 Screw the new lamp into position. Do not screw the lamp in too tightly.

12 Fit the cable into the restraint.

13 Reconnect the lamp cable.

14 Reinstall the lamp cover and click into place.

15 Reinstall the right side panel.

16 Click Next.

17 The absorbance photometer is initialized (automatic step).

18 A water/air calibration is performed (see below) (automatic step).

19 New water and air constants are automatically saved.

20 Click Finish.

Caution

- *If the halogen lamp is broken, remove the glass splinters with a vacuum cleaner. Remove the remaining rest of the halogen lamp carefully.*
- *While reconnecting the absorbance halogen lamp a small spark may be generated. This is not a malfunction and the energy of the system during this process is not enough to harm persons or damage the instrument.*

Water/air calibration

The system measures absorbance for 50 empty cuvettes at each wavelength. The system fills the same cuvettes with water and measures the absorbance again at each wavelength. Mean values are stored in the database and used to adjust results.

Replace probe B (or C)

Overview

For continuing accuracy, you must replace one or both of the probes when this service action becomes due. This service action can also be performed as a troubleshooting measure to overcome poor pipetting accuracy.

There is a separate service action to replace either of the two probes (B and C). You can replace individual probes, or you can replace both probes at the same time. Probe B is the one closest to you when you open the main front cover.

Duration

9 minutes

Interval

No interval. Status will be checked during Roche Service visits.

Tools and materials

- Probe set
- Activator on the ISE rack
- Protective gloves

Hazards

- The sample area, analyzer module, ISE module, fluid waste, cuvette waste, and transfer head are potentially infectious.
- Reagents can cause burns, irritation, and poisoning through skin contact.

Precautions

- Wear protective gloves.

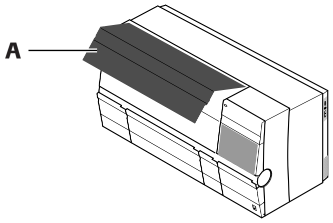
Further information

- Double-click the service action in the Due, All, or Begin of Day tab.
- Click Help in the dialog box.
- For general information about performing a service action, see Chapter 13, “Service action software”.

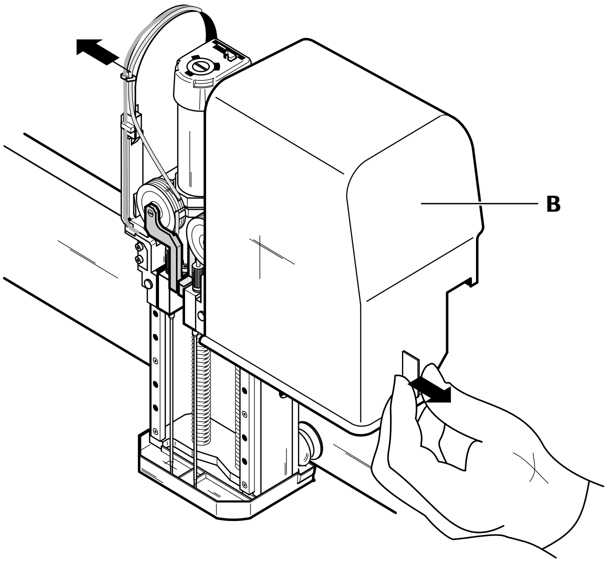
► To replace probe B (or C)

1. Select Replace probe B (or C) in the Service work area.
2. Click Perform.

   The Service Actions dialog box is displayed; follow the online instructions.
3. The transfer head is positioned in the sample area (automatic step).
4. Open the main front cover (A) to access the probes.



5 Remove the transfer head cover (B).

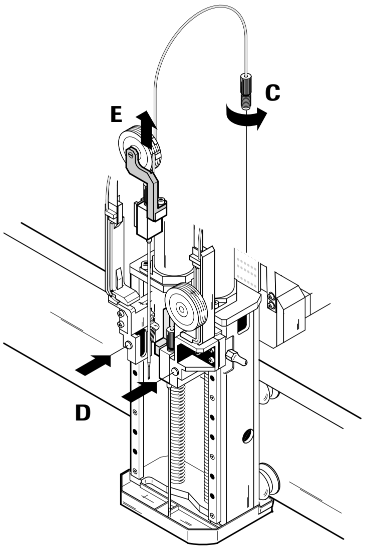


6 Disconnect the probe tubing from the transfer head fluid distributor (C).

7 Remove the probe and sample loop holder:

a. Press and hold down the button (D).

b. Push the probe upwards (E) until it disengages from the housing.

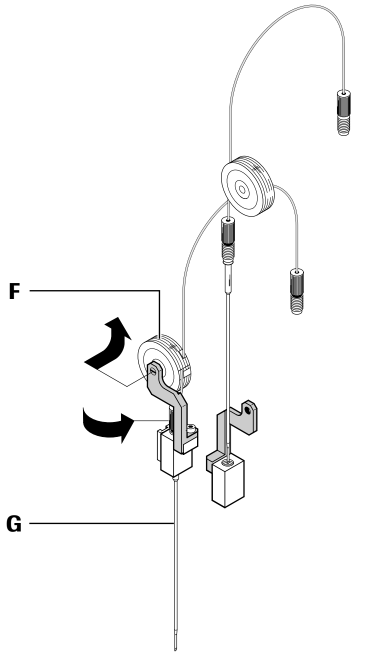


8 Disassemble the probe and sample loop structure:

a. Push the sample loop off the bracket (F).

b. Unscrew the probe (G).

c. Lift the probe out of the bracket.



9 Reassemble the structure using a new probe and sample loop.

Make sure to hold the screw thread of the probe in line with the probe holder to avoid damaging the screw thread.

10 Install the new probe and sample loop on the transfer head.

11 Reinstall the transfer head cover.

12 Click Next.

13 The transfer system is initialized (automatic step).

14 The probes are activated and the fluid system is primed (automatic step).

15 Click Finish.

Replace plunger tip dosage pipette B (or C)

Overview The dosage pipettes deliver accurate quantities of liquid for each test performed. To ensure the continuing accuracy of pipetting operations, you must replace the dosage pipette plunger tips before they become worn, as determined by the service action schedule.

Duration 10 minutes

Interval No interval. Status will be checked during Roche Service visits.

There is a separate service action to replace either of the two dosage pipette plunger tips (B and C). You can replace individual plunger tips, or you can replace both at the same time.

Tools and materials

- Teflon seal 250 µL
- Tip tool
- Scalpel
- Paper tissues
- Protective gloves

Hazards

- The sample area, analyzer module, ISE module, fluid waste, cuvette waste, and transfer head are potentially infectious.
- Reagents can cause burns, irritation, and poisoning through skin contact.

Precautions

- Wear protective gloves.

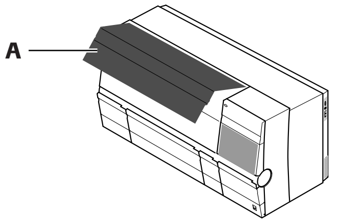
Further information

- Double-click the service action in the Due, All, or Begin of Day tab.
- Click Help in the dialog box.
- For general information about performing a service action, see Chapter 13, “Service action software”.

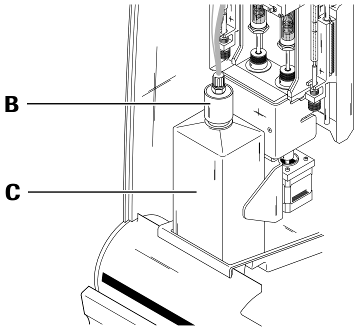
► **To replace the dosage pipette plunger tip**

1. Select Replace plunger tip dosage pipette in the Service work area.
2. Click Perform.

   The Service Actions dialog box is displayed; follow the online instructions.
3. The dosage pipettes are positioned (automatic step).
4. The probes are positioned inside the wash pipes (automatic step).
5. Open the main front cover (A) to access the pipettes.



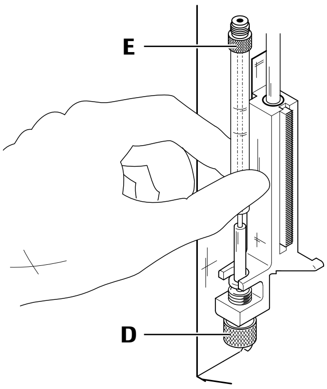
6 Remove the tubing (B) from the cleaner reservoir.



7 Remove the cleaner reservoir (C).

8 Loosen the dosage pipette locking bolt (D).

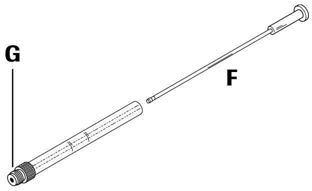
9 Unscrew the dosage pipette from the pipette fluid distributor (E).



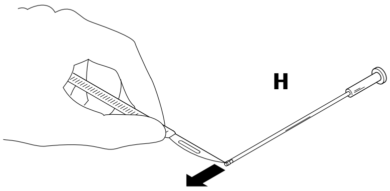
10 Pull the pipette forward to remove it from the module.

11 Pull out the piston (F).

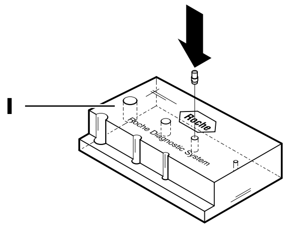
Make sure the seal cap is in place (G).



12 Cut and remove the plunger tip (H).



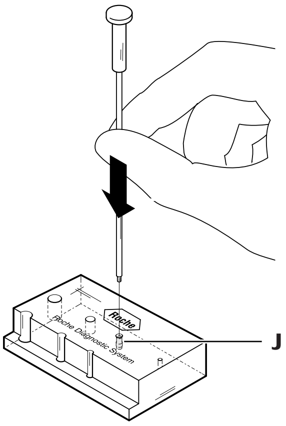
13 Insert the new tip into the tip tool (I).


I
Roche
Roche Diagnostic System

14 Press the piston into the tip (J).

Ensure that tip is flush with the piston (L).

If it is not (K), you must repeat the procedure.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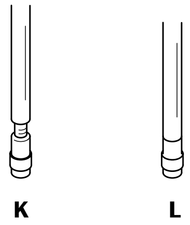
J

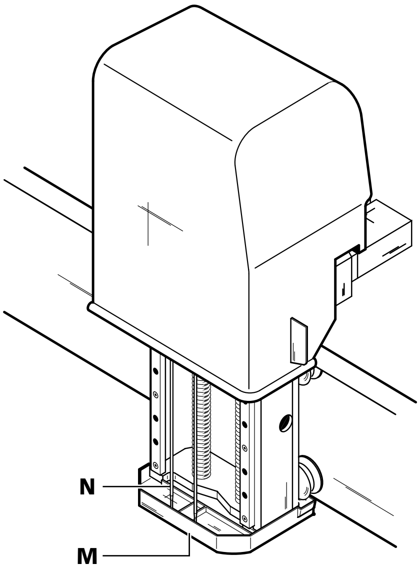


15 Insert the piston into the glass barrel and half-fill the pipette with water.

16 Reinstall the pipette.

Ensure that the seal cap (G) is correctly positioned.

17 Wipe away any drops of water from the pipette module, the probes (N), and the splash guard (M).



18 Reinstall the cleaner reservoir and the tubing.

19 Click Next.

20 The pipette module is initialized and the fluid system is primed (automatic step).

21 Click Finish.

If necessary, perform the service action Prime fluid system, and repeat it until no air bubbles are visible. (See page D-46.)

Replace dosage pipette B (or C)

Overview	The dosage pipettes deliver accurate quantities of liquid for each test performed. To ensure the continuing accuracy of pipetting operations, you must replace the dosage pipettes before they become worn, as determined by the service action schedule.
Duration	10 minutes
Interval	No interval. Status will be checked during Roche Service visits. There is a separate service action to replace either of the two dosage pipettes (B and C). You can replace individual pipettes, or you can replace both at the same time.
Tools and materials	• Pipette 250 µL • Pipette seal cap • Paper tissues • Protective gloves
Hazards	• The sample area, analyzer module, ISE module, fluid waste, cuvette waste, and transfer head are potentially infectious. • Reagents can cause burns, irritation, and poisoning through skin contact.
Precautions	• Wear protective gloves.
Further information	• Double-click the service action in the Due, All, or Begin of Day tab. • Click Help in the dialog box. • For general information about performing a service action, see Chapter 13, “Service action software”.

► To replace the dosage pipette(s)

1 Select Replace dosage pipette in the Service work area.

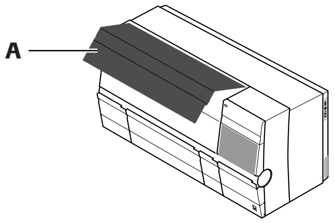
2 Click Perform.

The Service Actions dialog box is displayed; follow the online instructions.

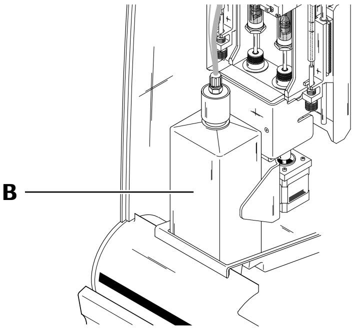
3 The dosage pipettes are positioned (automatic step).

4 The probes are positioned inside the wash pipes (automatic step).

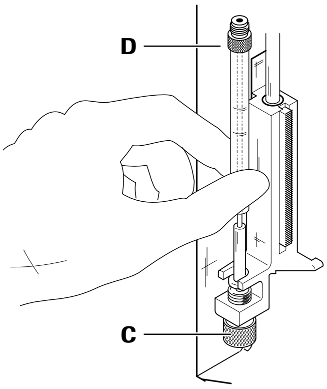
5 Open the main front cover (A) to access the pipettes.



6 Remove the cleaner reservoir (B).



7 Loosen the dosage pipette locking bolt (C).

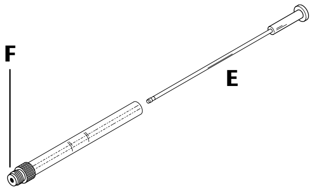


8 Unscrew the dosage pipette from the pipette fluid distributor (D).

9 Pull the pipette forward to remove it from the module.

10 Discard the used pipette according to your local requirements for the disposal of potentially hazardous waste.

11 Take the new pipette and pull out the piston (E).

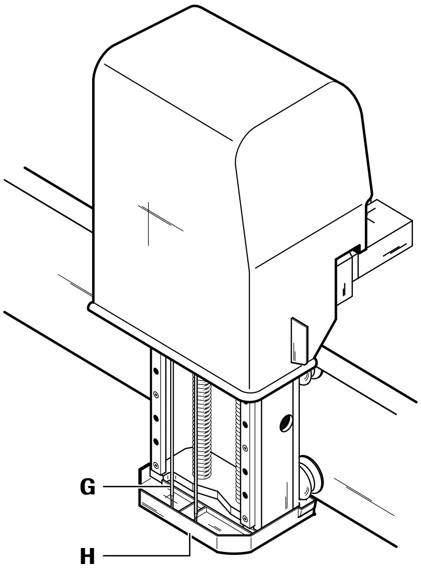


12 Insert the piston into the glass barrel and half-fill the pipette with water.

13 Install the pipette seal cap (F).

14 Reinstall the pipette.

15 Wipe away any drops of water from the pipette module, the probes (G), and the splash guard (H).



16 Reinstall the cleaner reservoir.

17 Click Next.

18 The pipette module is initialized and the fluid system is primed (automatic step).

19 Click Finish.

If necessary, perform the service action Prime fluid system and repeat it until no air bubbles are visible. (See page D-46.)

Replace external water reservoir filter

Overview	The liquid filter on the external water reservoir removes particulate matter from the water supply. You must replace this filter according to the service action schedule, or earlier (if, for example, the water pressure is too low or the water throughput is insufficient).
Duration	5 minutes
Interval	Every three months
Tools and materials	Liquid filter
Hazards and precautions	None
Further information	• Double-click the service action in the Due, All, or Begin of Day tab. • Click Help in the dialog box. • For general information about performing a service action, see Chapter 13, “Service action software”.

► **To replace the external water reservoir filter**

1 Select Replace external water reservoir filter in the Service work area.

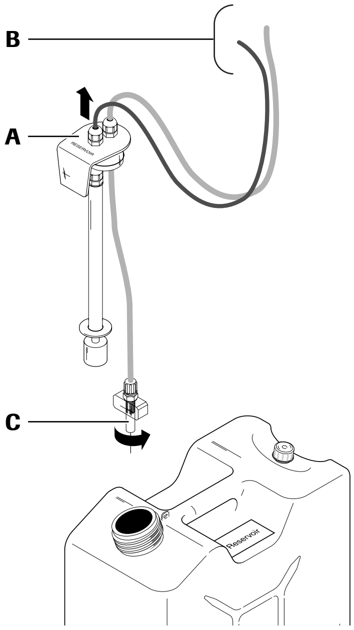
2 Click Perform.

The Service Actions dialog box is displayed; follow the online instructions.

3 Pull out the tubing adapter (A) from the external water reservoir.

Rest the adapter in a clean beaker to avoid contamination of the adapter and of any work surfaces.

Do not disconnect the suction pipe or the level switch from the instrument (B).



4 Replace the liquid filter (C).

5 Reinstall the tubing adapter.

6 Click Finish.

Managing data

The system generates a large amount of data that is stored on local disks. You must manage this data so that there is always enough space for the system to continue processing. The system stores most of its data in tables in an on-board database. The amount of data that can be stored in these tables is limited; also, even if the tables are not full, the system needs disk space for its own working data, for example, the system logs.

Database storage

Users have no direct control over the operation of the database, other than to define configuration parameters for the system. The space for the database tables is allocated dynamically and is reclaimed automatically when no longer required.

The performance of the database is essential to the performance of the system. The system issues messages to warn you if table space in the database is running out, or if performance is likely to be impaired. Follow the recommendations in the messages for dealing with these problems.

The following types of data are stored in the database:

- Orders - Orders are created by users or downloaded from the host system. These data are stored in the on-board database until it is deleted manually or purged.
- Results - The data from calculated test, calibration, and control results.
- Raw data - Data from the physical measurements made by one of the measuring modules when the system processes test orders, calibrations, and controls.
- Definitions - Database tables containing the current parameters for all test and related definitions on the system.
- Message log - This log contains the most recent messages.
- Journal - Results listed in the order in which they were pipetted.

Purging and deleting orders

After they have been processed, orders are kept on the system for a user-configurable time period. Orders older than this are automatically purged at the next BOD. You can set the time period in Configuration / Database / Automatic Actions (Delete Orders after). For example, if you specify Delete Orders after as two days, all orders older than two days will be deleted at the next BOD.

Purging orders removes the order ID from the Orders work area. This means that you can reuse an order ID after purging orders. In the Results work area, the order ID is still visible; the results are not removed. Each order ID is associated with a date and time so that you can always refer to a specific order by its number, its date, and its time stamp. This ensures that each order is unique.

You can only purge an order when:

- There are no pending tests belonging to this order.
- The associated results have been accepted.
- The associated results have been transmitted to the host, if you work with a host system.
- The associated samples have been removed from the system.

► To purge orders manually

1 Choose Tools > Purge Orders.

2 Click Yes on the Confirm Purge Orders dialog box.

► To delete orders automatically at BOD

1. Click Configuration on the navigation bar.
2. Double-click Database in the System group.
3. Click the Automatic Actions tab.
4. In the Delete Orders After box, type the number of days after which the order should be deleted.
5. Click OK.

Tips

- Type 0 (zero) to delete at the next Begin of Day all of today's orders, that is all orders defined between the time of the last and the next Begin of Day time.
- Type 1 to delete at Begin of Day all orders that were created more than 24 hours before Begin of Day time.

► To delete a single order

1. Click Orders on the navigation bar.
2. Click the Sample tab.
3. Type the order ID in the Order ID box and press Enter.
4. Choose Edit > Delete.

Purging results

The *Cedex Bio HT* analyzer is not designed to store safely large quantities of results on the system. As part of data management, you should periodically purge results manually. At least every 2 months is recommended.

By default, results from sample tests, calibrations, and controls are kept on the system indefinitely.

Purging removes completed results from the system. After purging, these results are no longer available on the system; you cannot retrieve them from the Results work area; any statistics that were calculated using the results are recalculated using the remaining results, when requested.

Purging results manually can take a considerable time. During this time, the system must remain in Standby; you should not attempt to insert a rack while a purge is in progress.

Preconditions

A sample test result is purged, provided that...

- The associated sample is not on board.
- The result is accepted.
- The result has been transferred to the host, if you work with a host system.

The associated order ID is purged as well, provided that...

- There are no pending test orders associated with this ID.

Tips

- Provided the above conditions are met, order IDs are deleted, even if tests were never performed for these orders, for example after inserting a rack with barcoded sample tubes and removing it again.
- Purge regularly, typically every two months.

Precaution

Before you purge results, you should archive your current calibration, control, and sample results (File > Archive Results).

What information is deleted?

When purging results, the following information is deleted:

- Results
- Calculated results that were derived from purgeable results
- Test orders
- Order IDs

What information is not deleted?

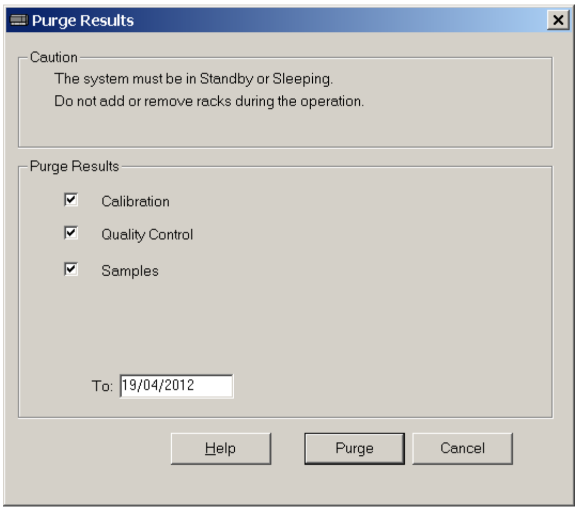
To make sure that the relevant calibration results are always available while processing orders (as long as the cassette is not empty), the following calibration results are kept when purging calibration results:

- The most recent calibration result for each test, even if it falls within the specified date range.
- Additional results are kept, depending on the calibration interval:
  - If calibration is due with each new cassette, a calibration result is kept for each started cassette.
  - If calibration is due when a new lot is started, one calibration result is kept for all cassettes of that lot.

► To purge results

1 Choose Tools > Purge Results on any work area.

2 The Purge Results dialog box is displayed.



Purge Results

Caution
The system must be in Standby or Sleeping.
Do not add or remove racks during the operation.

Purge Results
☑ Calibration
☑ Quality Control
☑ Samples

To: 19/04/2012

3 Select or clear the Calibration, Quality Control, and Samples check box to choose the kind of test results you want do delete.

4 In the To box, type the date up to which you want to delete the results. All results older than that date will be deleted.

5 Click Purge.

A status window is displayed while the results are being purged. The purging action may take quite some time, depending on the number of results that need to be deleted.

Click Stop to stop purging results. Note, however, that any results that were deleted before you pressed Stop are lost and cannot be restored.

► To delete a single result

1. Click Results on the navigation bar.
2. On any of the tabs, right-click an item, and choose Delete from the context menu. The Confirm Delete dialog box is displayed. The text on this box tells you exactly what data will be deleted.
3. On the Confirm Delete dialog box, click Yes.

Tip

Depending on your user rights, this option may not be available to you.

Archiving results

You can save results on the system for future reference. If you archive results in this way, you cannot reload them onto the system; you can only review them.

► To archive results

1. Click Results on the navigation bar.
2. Choose File > Archive.

   The Archive Results dialog box is displayed.
3. Select the type of results to archive and optionally a date range.
4. Click Archive.

   The Archive Result (File) dialog box is displayed.
5. Select the F disk drive, and specify a file name, file type, and a folder for the archive.
6. Click OK.

Note

This is not a backup facility.

Reviewing archived results

You can use the review facility to browse the archived results.

► To review archived results

1. Click Results on the navigation bar.
2. Choose File > Review.

   The Review (File) dialog box is displayed.
3. Select the folder, file type, and filename from where the results should be read.
4. Click OK.

   The Review Results dialog box is displayed.
5. Use Find to locate a specific test.
6. Click Close.

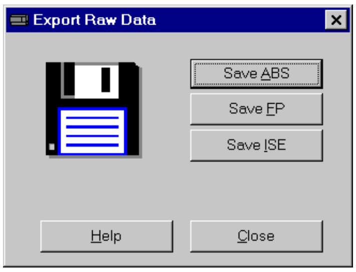
Exporting raw data

Most of the time, you do not need raw data to assess sample results. If you do need to keep raw data for a long time, you can export the data to CD/DVD or to a USB Memory Stick. You can select which measuring module you want to save raw data for and also the format for the saved data.

► To export raw data

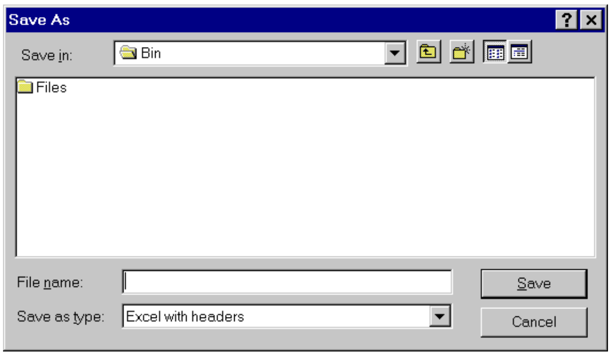
1. Click Configuration on the navigation bar.
2. Choose Tools > Export Raw Data

   The Export Raw Data dialog box is displayed.



3. Select the measuring module.

   The Save As dialog box is displayed.



4. Select the target directory, and type the file name.
5. Select the file format from the Save As type list.
6. Click Save.

Tips

- Exporting raw data does not delete the raw data from the database.
- Step 3 - If you need to save raw data for more than one measuring module, you must export the data separately for each measuring module.

Deleting raw data

Raw data are the numerical values of the physical measurements made by one of the measuring modules. Since each result comprises many measurements, the amount of raw data can become very large, very quickly. To prevent this from happening, you can choose either of two options:

- Delete Raw Data after accepting results.
- Delete Raw Data after n days.

► To delete raw data after accepting results

1. Click Configuration on the navigation bar.
2. Double-click Database in the System group.
3. Click the Automatic Actions tab.
4. Select the Delete Raw Data after accepting results check box.

5 Click OK.

► To automatically delete raw data after a certain period of time

1 Click Configuration on the navigation bar.
2 Double-click Database in the System group.
3 Click the Automatic Actions tab.
4 Select the Delete Raw Data after check box.
5 In the Delete Raw Data after box, type the number of days you want raw data to remain on the system.
6 Click OK.

Tips

- Type 0 (zero) to delete at the next Begin of Day all of today's raw data, that is all raw data generated between the time of the last and the next Begin of Day time.
- Type 1 to delete at Begin of Day all raw data that were generated more than 24 hours before Begin of Day time.

Definitions

The system automatically reserves enough space for test and related definitions in the database. When the system is set up, archive the definitions so that you can reload them quickly in the unlikely event of a damaged disk.

When you archive or load definitions, the data are stored in text files on a USB Memory Stick or on other media.

"Archiving and reloading definitions" on page G-19

Message log

The message log contains messages generated by the system. You can access this log by clicking Messages on the navigation bar, and then clicking the Message Log tab. By default, 200 messages are stored, but you can change this number to a maximum of 2000 messages (View Messages / Options).

The oldest messages are automatically deleted when the system needs space for new messages.

► To define the period during which message log information is kept

1 Click Messages on the navigation bar.
2 Click the Options tab.
3 In the Buffer Size box, type the number of messages that should be kept in the message log.

Journal

The journal logs information about tests in the sequence in which they were pipetted. The data in the journal older than a specified number of days are automatically deleted during BOD processing.

The journal is used most often in troubleshooting, to help identify carry-over problems between successive tests. Most of the time, you do not need to keep data in the journal for more than one day, unless there are specific problems that you need to address.

► To define the period during which journal information is kept

1 Click Configuration on the navigation bar.
2 Double-click Database.

3. Click the Automatic Actions tab.
4. In the Delete Journal after box, type the number of days for which log entries should be kept in the journal.

Flags in the journal

Take care when evaluating results that are flagged in the journal. The flag listed in the Journal for a specific test is not necessarily the final flag for that test. The flag in the Journal is a temporary flag that was active when the pipetting took place. This flag is often overwritten or removed from the final result. To review flags for a result, use the Sample, Calibration, or Quality Control tabs in the Results work area.

Non-database storage

Some data are stored on disk, and are not part of the database:

- Archived definitions - Data files containing the parameters (but not necessarily the current ones) for all test and related definitions on the system.
- System logs - Data files used by the system to store data so that, for example, the system can restart after an electrical, mechanical, or database failure. Generally not accessible to users.
- Backup data - Data files used to restore the system after a disk failure. These data are stored on drive D.

Backing up your data

The system automatically backs up the database as a BOD service action. The backup data is stored on disk D. You can also request this service action manually, in the Service work area.

The purpose of the backup is to ensure that you can reload all system data - including all definitions and results up to the last backup - if disk drive C were to fail. The system can then be restarted as it was at the last backup.

“Backup database” on page D-48

Database messages

If you see the message 3731, part of the database allocation for a particular resource is at least 80% full. The most likely causes are that the system is:

- Storing too many orders
- Storing too many results
- Keeping raw data too long

Failure to deal with this message promptly can lead to poor system performance. In extreme cases, the system may stop.

Message 3731 may reappear during the next BOD action if remedial action is not taken before the BOD.

Recommended actions

► **If you see message 3731**

1. Purge orders (Tools > Purge Orders), if you have not already done this as part of your daily startup.
2. Purge results (Tools > Purge Results).

3 Delete any unwanted unaccepted results.

4 Reduce the time period over which raw data is kept (Configuration / Database / Automatic Actions). Specify a value of less than six days; consider specifying one day, and exporting the raw data to drive F.

5 You can also consider reducing the time that journal data is kept (Configuration / Database / Automatic Actions) and reducing the size of the message log (View Messages / Options).

6 If the problem reoccurs after completing steps 1 through 5, contact Roche Service.

Where to save your data

The disk drives are organized as follows:

Drive	Contains…
A	Archived or exported data, updates.
USB drive	Archived or exported data, updates.
B	Not used.
C	Programs and system data.
D	Backup data.
E	CD-ROM.
F	User data, including archive data.

Tips

- Use drive F for all your own archive data. You can save any definitions, results, and raw data still on the system for future reference.
- Do not store any of your own data on drives C and D, otherwise your system may run out of disk space.

Transmitting data to the host

In normal operation, for systems that are enabled for host communication, accepted results are uploaded to the host after the host has sent a query to the system. After result upload the results are labeled internally as “completed”.

Transmitting all results

If you need to retransmit results to the host, choose Tools > Retransmit All Data from the menu bar. This command retransmits all results on the system, even if you are only interested in one or two.

- *Use Configuration / Processing / Result Output to enable or disable the function Retransmit All Data.*
- *Depending on the content of the database, the retransmission of all data can take multiple hours or days.*

Transmitting selected results

You can select one or more individual results, results for a specific order, or for a specific date to be transmitted to the host.

► To transmit selected results

1. Use Configuration / Processing / Result Output to select Host Interface Transmission for the kind of result you want to transmit.
2. Select the required results in the Results work area.
3. Choose Tools > Transmit Selected Data from the menu bar.

Example: Transmit specific sample results

1. Use Configuration / Processing / Result Output.
2. Check that Sample is enabled.
3. In the Results work area, click the Sample tab.
4. Select the required folder.
5. Click ⊞ to open the folder.
6. Select the required results.
7. Choose Tools > Retransmit Selected Data from the menu bar.

   The Confirm Retransmit Data message is displayed.
8. Click Yes.

   A Retransmit to Host message is displayed.
9. Check that the required data were sent.
10. Click OK.

Tip

- Step 7 - The command is shaded unless your selection contains one or more results.
- Do not change any host interface settings unless you are sure they are incorrect.

Troubleshooting E

Part E describes messages generated by the system, what they mean and how to deal with them. It also describes specific problems and gives step-by-step procedures on how to deal with them.

Messages

General problem-solving techniques

This chapter explains how to identify and interpret messages, and suggests ways of reacting to these messages.

In this chapter *Chapter* **15**

About messages E-4

  Messages button E-5

New Messages tab E-6

Message Log tab E-7

Options tab E-8

Working with messages E-9

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  Printing messages E-10

Putting the system into Standby E-12

Stopping and restarting the system E-13

  Stop processing E-13

  Shutting down the system E-15

About messages

Messages inform you about errors or other events that have occurred on the system. The icon displayed on the message dialog box reflects the severity of the problem:

Symbol	Meaning
ℹ	Information message: Often a prompt to ask you if you really want to do something.
⚠	Warning: Alerts you to some condition or consequence, but the system as a whole can keep running. Some messages of these types may mean one or more measurement modules may not be able to run tests.
✖	Critical error: The system cannot continue. You must fix the problem and then restart the system.

All messages that generate a dialog box are listed on the New Messages tab on the View Message dialog box.

► To react to a message

1 On the message dialog box, click 🔈 to turn off the audible alarm, if necessary.

2 Read the message and take appropriate action.

3 Click Help for additional information, if available.

4 Click Report if you want to create and save a problem report.

👁 *"Creating a problem report" on page E-44*

5 Click Close when you have read the message.

6 Confirm the message.

👁 *"Confirming messages" on page E-9*

Tips

- If you need to refer to the message again after confirmation, use the Message Log tab.

  👁 *"Message Log tab" on page E-7*

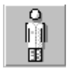
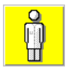
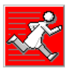
- All messages that generate a dialog box are listed on the New Messages tab on the View Message dialog box. Double-click a message for more details.

► To get Help on a particular message

👁 *"Message Help" on page A-68*
"Reacting to a hardware message" on page E-29

Messages button

The background color of the Messages button shown on the navigation bar indicates whether there are messages waiting to be viewed. The background color also indicates the severity of the message.

Button	**Background**	**Meaning**
	Gray	The messages that are occurring need no action from the user.
	Yellow	Warning messages waiting to be dealt with. You should deal with these messages promptly, to ensure that a critical situation does not develop.
	Red flashing (Running messenger)	Error or critical messages waiting to be dealt with. You should deal with the causes of these messages immediately.

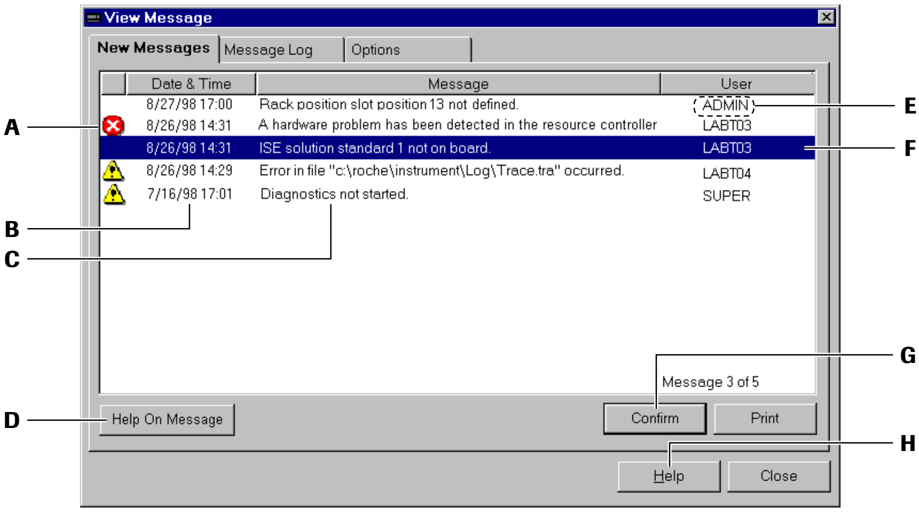
Clearing the Messages button

You can clear the red and yellow versions of the Messages button by confirming all warning, error, and critical messages.

👁 *"Confirming messages" on page E-9*

New Messages tab

Use the New Messages tab on the View Message dialog box to review all currently unconfirmed messages (listed by time).



	Date & Time	Message	User
	8/27/98 17:00	Rack position slot position 13 not defined.	ADMIN
✖	8/26/98 14:31	A hardware problem has been detected in the resource controller	LABT03
	8/26/98 14:31	ISE solution standard 1 not on board.	LABT03
⚠	8/26/98 14:29	Error in file "c:\roche\instrument\Log\Trace.tra" occurred.	LABT04
⚠	7/16/98 17:01	Diagnostics not started.	SUPER

A *Icon showing the severity of the message (if any).*

B *The date and time when the message was created.*

C *Short message text.*

D *Click to get Help on the selected message (if available).*

E *Name of the user logged-on at the time the message was created.*

F *The selected message. Double-click to display details on this message.*

G *Click to confirm the selected message.*

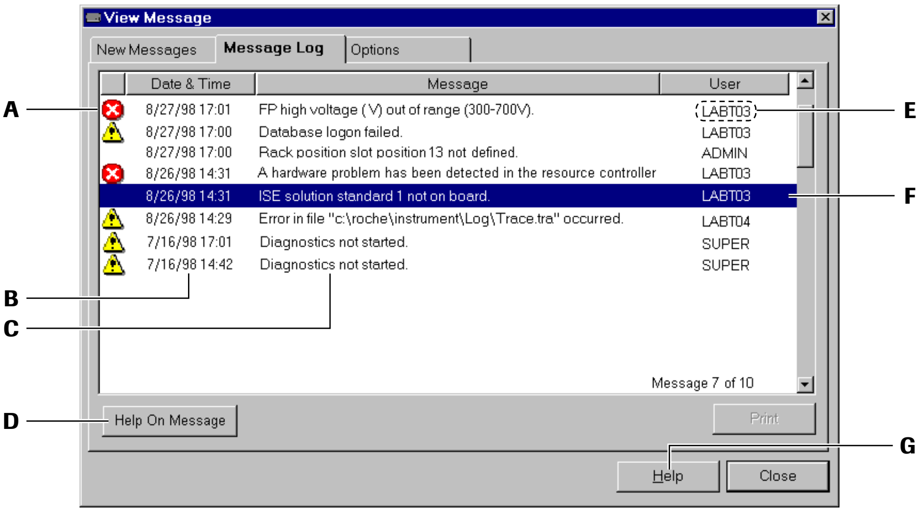
H *Click for Help on this dialog box (this does not give Help on the selected message).*

Tips

- You click Confirm to inform the system that you have fixed the problem in the message.
- If you have not fixed the problem, the system will either not restart, or the same message will reappear again, if the same conditions are met.
- Confirmed messages are automatically transferred to the message log.

Message Log tab

Use the Message Log tab on the View Message dialog box to review messages that you (or other users) have already confirmed as resolved. Double-click any message to display the Message Detail dialog box.



	Date & Time	Message	User
✖	8/27/98 17:01	FP high voltage (V) out of range (300-700V).	LABT03
⚠	8/27/98 17:00	Database logon failed.	LABT03
	8/27/98 17:00	Rack position slot position 13 not defined.	ADMIN
✖	8/26/98 14:31	A hardware problem has been detected in the resource controller	LABT03
	8/26/98 14:31	ISE solution standard 1 not on board.	LABT03
⚠	8/26/98 14:29	Error in file "c:\roche\instrument\Log\Trace.tra" occurred.	LABT04
⚠	7/16/98 17:01	Diagnostics not started.	SUPER
⚠	7/16/98 14:42	Diagnostics not started.	SUPER

Message 7 of 10

A *Icon showing the severity of the message if any.*

B *The date and time when the message was created.*

C *Short message text.*

D *Click to get Help on the selected message (if available).*

E *Name of the user logged-on at the time the message was created.*

F *The selected message. Double-click to display details on this message.*

G *Click for Help on this dialog box (this does not give Help on the selected message).*

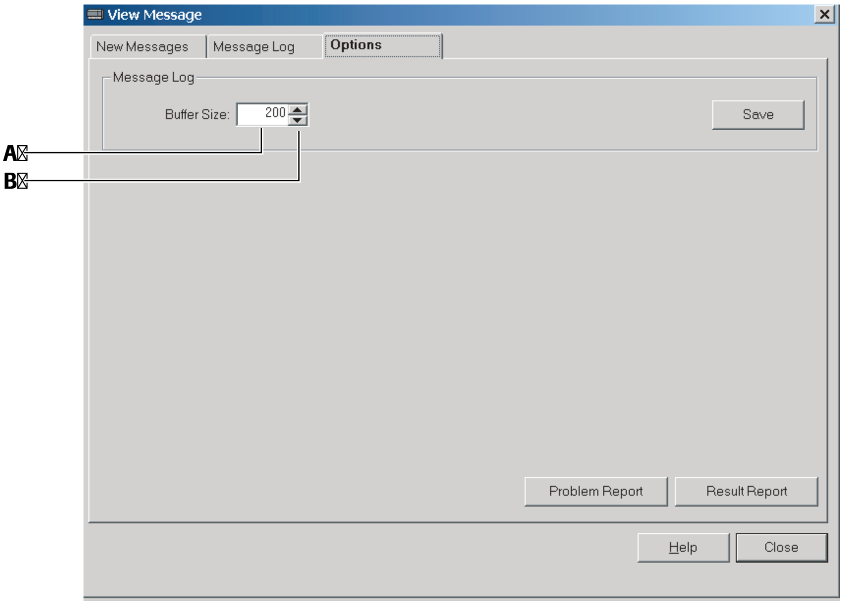
Tips

- The message log contains only confirmed messages.
- By default, 200 messages are stored, but you can change this number to a maximum of 2000 messages (View Messages / Options).
- The oldest messages are automatically deleted when the system needs space for new massages.

Options tab

Use the Options tab to specify the maximum number of messages stored in the message log. Type a number in the Buffer Size text box and click Save.

You can increase or decrease the size of message log buffer as required. A buffer size of 100 means that a maximum of 100 messages are stored in the log. The system saves the most recent messages and, if the log is full, deletes the oldest messages to make way for the more recent ones.


View Message
New Messages
Message Log
Options
Message Log
Save
Problem Report
Result Report
Help
Close
A
B

Buffer Size: 200

A *Specifies the number of messages in the message log.*

B *Click to change the size of the message log.*

The Options tab is also used to save the Problem and Result Reports for troubleshooting purpose.

Working with messages

You can confirm messages, display or print details on a message, review confirmed messages, or display Help on a message.

Chapter 4, "Online Help"

Confirming messages

A shortened form of each message is stored on the New Messages tab on the View Message dialog box. When you confirm a message, it is automatically removed from the New Messages tab and transferred to the Message Log tab. The system can carry on running even if there are unconfirmed messages.

Recommendation Do not confirm a message until you are sure that you have resolved the problem that caused it to appear in the first place.

The running man on the Messages button remains until you confirm:

1. The message that caused it to be displayed.
2. All subsequent messages that could have caused a running man to be displayed.

► To confirm a message

1 Click Messages on the navigation bar.

The View Message dialog box is displayed.

2 Click the New Messages tab.

3 When you have fixed the problem, select the message and click Confirm.

The selected message is automatically transferred to the message log.

Tips

- Double-click a message to get more information.
- Follow any Help or instructions contained in the message to remove the cause or causes of the message (if you have not already fixed the problem from the original message dialog box).
- If you need to refer to the message again, use the message log.

Displaying message details

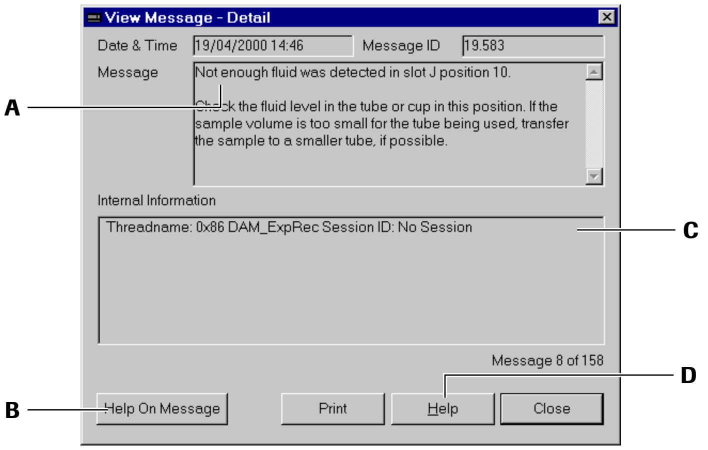
► To display message details

1 Click Messages on the navigation bar.

2 Click either the New Messages or Message Log tab.

3 Double-click a message.

The View Message - Detail dialog box is displayed.



Date & Time: 19/04/2000 14:46

Message ID: 19.583

Message: Not enough fluid was detected in slot J position 10.

Check the fluid level in the tube or cup in this position. If the sample volume is too small for the tube being used, transfer the sample to a smaller tube, if possible.

Internal Information: Threadname: 0x86 DAM_ExpRec Session ID: No Session

Message 8 of 158

A *Long text of the message.*

B *Click for Help on this message.*

C *Service and diagnostics information.*

D *Click for Help on the dialog box (not message Help).*

Printing messages

You can print a list of messages from either the New Messages tab or the Message Log tab.

► To print a list of new messages

1. Click Messages on the navigation bar.

   The View Message dialog box is displayed.
2. Click the New Messages tab.
3. Click Print.

Tip

This procedure prints only non-confirmed messages (for problems that have not yet been resolved).

► To print the message log

1. Click Messages on the navigation bar.

   The View Message dialog box is displayed.
2. Click the Message Log tab.
3. Click Print.

Tip

The message log contains messages that have been confirmed (and therefore have been automatically removed from the list on the New Messages tab).

Putting the system into Standby

How you do this depends on the state the system is already in. The Status button on the navigation bar tells you what the system state is.

Standby	**Operating**	**Sleeping**	**Service actions**	**Initializing**

If the system is in Operating state

1 Click Stop.

2 In the Stop Action dialog box, click Sampling Stop.

3 Click OK.

If the system is in Sleeping state

1 Click Start.

2 The system performs a partial initialization and then goes into Standby.

If the system is performing BOD actions or service actions

Wait until the BOD actions or service actions have finished. The system returns to Standby automatically.

Tip: You cannot use Stop to force the system into Standby when it is performing BOD actions or service actions.

If the system is Initializing

Wait until initialization is complete.

Stopping and restarting the system

You sometimes need to stop the system while troubleshooting.

There are two levels of stopping:

1. Stop and continue processing
2. Shut down and restart the system.

Which method is appropriate depends not only on what you need to do in terms of corrective action, but also what the system is doing (the system state) and how your throughput will be affected.

Check the messages and online Help to see which method is recommended for a particular case.

The procedure for a complete shutdown and restart of the system consists of the following steps:

1. Stop processing
2. Shut down the system
3. Restart the system
4. Initialize the system
5. Restart processing

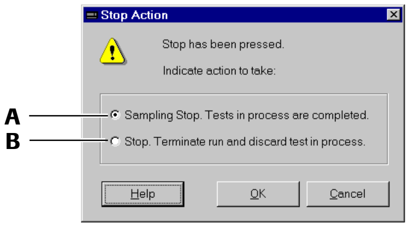
Stop processing

Stop

If the system is in the Operating state (for example, when it is processing tests) Click Stop on the navigation bar to interrupt sampling immediately or stop sampling as soon as the current actions are finished.

The precise function of the buttons depends on the current system status.

When clicking Stop, the Stop Action dialog box is displayed, which offers the Sampling Stop and Stop options:



Stop has been pressed.

Indicate action to take:

● Sampling Stop. Tests in process are completed.

○ Stop. Terminate run and discard test in process.

A *Stop pipetting samples but finish processing tests that are already in progress.*

B *Stop all system operations immediately. The system aborts all current activities. The system may need special attention before it can resume its normal operation.*

Tips

- If the system is already in Standby when you click Stop, it goes into Sleeping.
- If you stop the run immediately, all the partially-run tests are stopped. In practice, this means you lose all the reagent, control, calibrator, and sample material for any tests that have been started but not yet completed.

- The background color of the Status button tells you what the current system state is; green means Operating (unless there is a resource alert).

  “System states” on page A-42

- You can also use F12 to stop the processing.

Restart processing

The Start button serves to start or restart a run.

When the system is in the Stopped, AutoService, or Operating status, the text of the Start button changes to Restart.

Tips

- Clicking Restart causes the system to perform a re-scheduling of all sample orders. For example, clicking Restart after inserting a new rack into the system while in Operating status, causes the system to start pipetting on the sample rack that is positioned furthest to the left.
- You can also use F11 to start or restart the processing.

Re-initializing

When the system is in Standby, you can re-initialize, if necessary. Sometimes you will be asked to do this in the recommended actions for a particular message. You would also need to do this if your troubleshooting procedure caused you to knock (or move) an initialization post, for example.

► To re-initialize the system

1. Click Stop on the navigation bar to put the system into Standby state.
2. Click Service on the navigation bar.
3. Choose Tools > Initialize System.

   System initialization takes a few minutes to complete.
4. Click Restart, if necessary.

Tips

- The system must be in Standby or Fatal Error state when you initialize.
- The dialog box displayed after you click Restart is not listed here.

  “Stop processing” on page E-12

  In all messages and recommended actions in the Help, your reaction to this dialog box is assumed.
- Step 4 is not required if Auto Start is enabled (in Configuration / General / System).

Shutting down the system

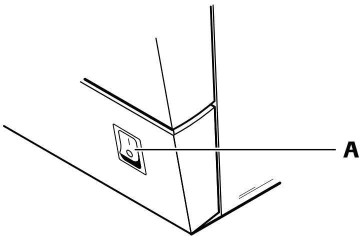
Shutting down the system means that the *Cedex Bio HT* program is closed down and the instrument and computer are switched off.

► To shut down the system

1. Choose File > Shut Down.

   Your are asked to confirm.

   The computer is switched off automatically.



2. Switch off the instrument at the main switch (A).

   After shutdown:

   - All tests and procedures in progress are stopped.
   - The *Cedex Bio HT* main window is closed.

Tip

You can also perform a shutdown by pressing Alt + F4.

After shutdown, certain maintenance procedures will be run automatically from a separate standby power supply.

Restarting the system after shutdown

You should perform a restart only after the screen has become dark.

► To restart the system

1. Switch on the instrument at the main switch.
2. Switch on the computer.

   The system undergoes the complete startup procedure. The *Cedex Bio HT* program is automatically restarted. Log on (Shift + F3) when the Log On dialog box is displayed.

Tips

- After restarting:
  - Windows XP is automatically restarted. You do not have to log on to Windows XP.
  - The *Cedex Bio HT* program is automatically started.
  - The system is re-initialized.
- When you log on, type in your user ID and password as usual. You must rerun tests that were in progress when the system was stopped.

Troubleshooting

General problem-solving techniques

This chapter explains how to identify and fix problems that can affect the running of the *Cedex Bio HT* analyzer. It explains how to view and respond to system-generated messages and how to troubleshoot problems that do not generate messages. A description of how to identify and replace fuses is also included.

If you encounter any problems that you cannot resolve, information about contacting Roche Service is also provided.

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Introduction

Effective troubleshooting on a *Cedex Bio HT* system requires a good understanding of all basic operating procedures for the instrument and the system software. However, you can avoid most common problems if you observe the recommended procedures at all times and if the operating environment is effectively controlled.

For new users in particular, there are the usual familiarization problems including:

- Connecting various parts of the computer system, if necessary.
- Locating the main switch and function keys.
- Starting up the program and logging on.
- Finding your way around the user interface.

All the information you need is available either in the User Manual or in the online Help.

For details on flags, error messages, and recommended actions for ISE related problems, see "Flags and user actions" on page F-41 and "General ISE troubleshooting" on page F-49.

Information about problems

The user interface keeps you informed about the status of the instrument as a whole, and about particular hardware, software, and chemistry problems as they arise. It does this through:

- Messages displayed on the screen.
- Status work area.
- Buttons on the navigation bar.
- Flags on results from samples, calibrations, and controls.

You can also often see that something is wrong before any results are produced. A dripping probe for example, will affect the generated results.

Preventative maintenance

The most common sources of problems are related to service actions and water purity:

- For service actions, the main problem is a failure to keep to the maintenance schedules as defined by the service actions. Ensuring that the instrument is correctly maintained is the most effective thing that you can do to reduce problems.
- Poor water quality can cause problems over a long period of time and can be difficult to troubleshoot especially if the water quality varies from day to day.

"System water quality is unsuitable" on page E-27

Start-up problems

This section lists potential problems arising from start-up or system initialization.

► Computer mains power connector is not plugged in

1. Insert the plug into the socket.
2. Switch on the instrument
3. Switch on the computer.

► Instrument main power cord is not plugged in

1. Switch off the instrument.
2. Insert the plug into the socket.
3. Shut down the computer.

   The computer is switched off automatically.
4. Switch on the instrument.
5. Switch on the computer.

► Laboratory power supply has been interrupted

1. Check other electrical power sources and inform your in-house service personnel.
2. When the power is re-established, the system will restart automatically; wait until the system is initialized.

► System cannot initialize due to a fault in one or more of the analyzer modules

1. Check the displayed message(s) and take the necessary action.
2. If the initialization is incomplete and no error is shown, contact Roche Service.

► System remains inactive in Operating mode

Check all the resources on the Samples, Cassettes, Analyzer, and ISE tabs of the Status work area.

Blocked orders, tests, calibrations, or controls

The following main conditions must be fulfilled before you can successfully run any test on the *Cedex Bio HT*:

- All required reagents, diluents, cleaners, calibrators and controls are on board and have enough volume to run the test.
- The last calibration and control results are accepted (for calibration and control tests).
- The sample is on board and has enough volume to run the test.
- The test and the measurement modules are enabled.
- The instrument and the measurement modules are in an error-free state.

If any of these conditions are not fulfilled, the test will be blocked and the cause must be eliminated.

► To check the cause of blocked orders, tests, calibrations, or controls

1. Click Orders on the navigation bar.
2. Click the Worklist tab.
3. Open the Blocked folder and select a blocked order.

   Detailed information of the selected order is displayed in the area on the right.
4. Make a note of the Blocked Status Text and look up the corresponding recommended actions in the list below.

Tips

- Double-click a blocked order in Results / Validate to see the Blocked Status Text.
- To get help on a blocked item, select the Blocked Status Text and press F1.

Cassettes and cleaner

Not on board

- Reagent not on board
- Cleaner not on board

Recommended action

1. Place the required reagent or cleaner cassette in a cassette rack.
2. Insert the cassette rack into the cassette area.

Empty

- Reagent is empty
- Cleaner empty

Recommended action

1. Locate the rack position of the empty reagent or cleaner cassette in Status / Cassettes.
2. Remove the cassette rack from the cassette area.
3. Replace the empty cassette with a new one.
4. Re-insert the cassette rack into the cassette area.

Not Enough for Worklist

The cassette is loaded, but there is not enough material to run all the tests in the current worklist.

Recommended action

Place an additional cassette of the same kind on a rack.

Calibrators, controls, and diluents

Not on board

- No calibrator on board
- Control not on board
- Diluent not on board

Recommended action

1. Load the required calibrators, controls, or diluents on their correct rack positions.
2. Insert the rack into a free slot in the sample or cassette area.

Tip

To check the correct calibrator, control, or diluent position, do one of the following:

- Open the Not on Board folder in Status / Missing & Blocked, to see the missing calibrators, controls, or diluents and their correct rack positions.
- Click a test folder in Status / Test Status, to see the calibrator, control, or diluent information of the selected test.
- If you see, for example, a status of Diluent not on board, and you replace the diluent while the system is in Standby, the values for Status and Next Cal. in the Test group are not updated until the system is in Operating status. The information in the Diluents group, however, is updated immediately. You may have to click (Re)Start on the navigation bar to get the system to Operating mode.

Empty

- Calibrator empty
- Control empty
- Diluent is empty

Recommended action

1. Open the Empty folder in Status / Missing & Blocked, to see the empty calibrators, controls, diluents, and their correct rack positions.
2. Remove the required rack from the instrument.
3. Refill the empty calibrator, control, diluent, and cups or tubes.

4 Re-insert the rack into a free slot in the sample or cassette area.

Not accepted

- Last calibration is not accepted
- Last control not accepted

The last calibration or control result was not accepted and a further calibration or control request has been made, either by the system (as a result of a cassette change, for example), or by the user. (Note that you can only request a further calibration or control once the calibration or control results are accepted, you may request a rerun, though.)

Recommended action

1. Accept the last calibration or control results in the Validate tab in the Results work area.
2. If the last calibration or control result was not accepted because it was flagged, follow the recommended action for the displayed flag.

Accepting flagged calibrations without taking appropriate action will cause all subsequent sample results also to be flagged.

No definition

- No calibration definition available
- No control definition available

Recommended action Install the required calibration or control definitions. See Online Help for details.

Samples

No fluid

- No fluid in sample cup.

No fluid level was detected in a tube or cup. Possible reasons are:

  - The tube or cup is empty.
  - The tube or cup is overfilled.
  - Wrong tube definition.

Recommended action Do one of the following:

- Refill the sample tube or cup.
- Remove some sample from the tube or cup.
- Check the parameters Trigger Point and Lower Sample Margin in Configuration / Lab / Sample Tubes.

Unknown fluid

- No sample type was detected.

Possible reasons are:

  - The sample type is not known.
  - Position conflict between two samples.
  - The barcode on the tube could not be read.

Recommended action Do one of the following:

- Assign the sample to a position on the rack

- Remove the rack and assign the sample to a new position on the rack.

  👁 *"Assigning samples to racks" on page B-96*

- Remove the clot.
- Manually enter the barcode information:

  If you work with a host system:

  1. Remove the rack and identify the missing information.
  2. Re-insert the rack after identifying the tubes whose barcode could not be read.
  3. Use the Place Items dialog box to define the orders and tests, and for assigning the samples to rack positions.

  If you work without a host system:

  1. Remove the rack and identify the missing information.
  2. On the Sample tab of the Orders work area, create the orders and tests that were not read from the barcode
  3. Assign the samples to the rack positions.
  4. Re-insert the rack into the system.

Tests

Disabled

- Test disabled

Possible reasons are:

- ◦ Test was manually disabled.
- ◦ Test was automatically disabled due to a flagged calibration or quality control result. This is the case if the flag action is set to Stop Test in Configuration / Result Handling.

Recommended action

1 Open Status / Test Status.

2 Select the required test.

3 Select Test Enabled.

Tip

Check if the rules defined in Configuration / Result Handling apply to the workflow in your laboratory and change the result handling if applicable. See the Online Help for details.

Aborted

- Test aborted

Test was aborted either by stopping the run and selecting "STOP. Terminate Run and discard tests in progress" or by switching off the instrument.

Recommended action Restart the run.

ISE

Not on board

- Activator not on board
- ISE Deproteinizer not on board
- ISE Etcher not on board
- No ISE solution available

Recommended action

1. Open the Not on Board folder in Status / Missing & Blocked, to see the solutions that are not on board and their correct rack positions.
2. Remove the ISE rack from the instrument.
3. Load the required Activator, ISE Deproteinizer, ISE Etcher, or ISE solutions on their correct ISE rack positions.
4. Re-insert the ISE rack into slot O.

   The ISE Rack Replaced dialog box is displayed.
5. On the dialog box select the ISE solutions that you have replaced.

Leave the check boxes cleared for ISE solutions you have not replaced.

Empty

- Activator is empty
- ISE Deproteinizer is empty
- ISE Etcher is empty
- ISE solution is empty

Recommended action

1. Open the Empty folder in Status / Missing & Blocked, to see the empty Activator, ISE Deproteinizer, ISE Etcher, or ISE solution and their correct rack positions.
2. Remove the ISE rack from the instrument.
3. Refill the empty Activator, ISE Deproteinizer, ISE Etcher, or ISE solution.
4. Re-insert the ISE rack into slot O.

   The ISE Rack Replaced dialog box is displayed.
5. On the dialog box select the ISE solutions that you have replaced.

Leave the check boxes cleared for ISE solutions you have not replaced.

Not ready

ISE module is not ready

The ISE module is not initialized. Possible reasons are:

- ◦ The last ISE initialization was not successfully completed.
- ◦ Not all required solutions are available, for example Activator or Std-1.
- ◦ The ISE module was recently enabled but no ISE initialization was performed.

Recommended action

- Make sure all solutions are on board.

- Perform the service action Initialize ISE module in Service / All.

Disabled

- ISE module disabled

The ISE module was disabled manually.

Recommended action

1. Open Status / ISE.
2. Select Enable ISE Module to enable the ISE measurements.

Tip

The instrument must be in Standby for enabling the ISE module.

No electrode

- No ISE Electrode

The ISE electrode is not defined or it is disabled.

Recommended action

1. Open Configuration / General / ISE.
2. Select the required electrode setting.
3. Click OK.
4. Open Status / ISE.
5. Select Potassium or Sodium to enable the required electrodes.

Error

- Error in ISE module

Hardware error in the ISE module.

Recommended action

1. Check for new hardware error messages in View Message / New Messages.
2. Select the message and click Help on Message to open the Online Help.
3. Follow the recommended actions of the selected message.

Hardware errors

Abs. error

- Error in Abs. photometer

Hardware error in the absorbance photometer module.

Recommended action

1. Check for new hardware error messages in View Message / New Messages.
2. Select the message and click Help on Message to open the Online Help.
3. Follow the recommended actions of the selected message.

FP error

- Error in FP photometer

Hardware error in the fluorescence polarization module.

Recommended action

1. Check for new hardware error messages in View Message / New Messages.
2. Select the message and click Help on Message to open the Online Help.
3. Follow the recommended actions of the selected message.

FP disabled

- FP photometer disabled

The FP photometer was disabled.

Recommended action

1. Open Configuration / General / System.
2. Select FP photometer to enable the FP measurements.

Tip

The instrument must be in Standby for enabling the FP photometer.

Fatal error

- Fatal HW error

The system has a fatal hardware error. The robotic transfer system, the ISE module and the analyzer including absorbance and FP photometer are not working due to a serious hardware problem. No measurement of tests is possible.

Recommended action

1. Check the status of the system in Status / Analyzer.
2. Shut down and restart the system.
3. If the problem reoccurs, Call Roche Service.

Results

This section lists those problems that may occur when results are obtained from the instrument.

Quality control results out of range

Quality control results are obtained but they are outside the expected range for the test.

► Control or a diluent in the wrong position

1. Use Status / Missing & Blocked to check which items are missing.
2. Use Status / Samples to check the current positions of all on-board controls and diluents.
3. Replace the controls or diluents in their correct positions as required.

► Control material has deteriorated or was incorrectly reconstituted

1. Use Status / Samples to check the current positions of all on-board controls.
2. Replace the controls with fresh or freshly-prepared material in the correct rack positions.

► Lot-specific assigned values are not correct

- Check the values in Configuration / Controls / Lot.

► Pipetting error

The volume of fluid delivered by the dosage pipettes is incorrect.

👁 *"Leakage" on page E-30*
"Air bubbles in one or more pipettes" on page E-31
"Dripping pipettes" on page E-31
"Dripping probes" on page E-32

► Reagent in the cassette has deteriorated

1. Check the cassette expiration date in Status / Cassettes.

   If the cassette has reached its expiration date, replace it with a new cassette when the rack is released.
2. Check the results of the last calibration or control.

   If the results deviate significantly from the previous calibration or control, order a new calibration or control.

   If the results are still wrong, check the calibrator or the control material. If these are OK, replace the reagent cassette.
3. Check when the next calibration is due (Status / Test Status).

   If the due time is some time away and the last calibration was performed some time back, order a new calibration.

Test results not reproducible

Results are obtained but are frequently flagged. In particular, when a particular test is rerun, the results are not consistent with earlier values.

► Air bubbles or foam on the surface of the sample

1. Carefully remove air bubbles or foam from the surface of the sample.
2. When transferring samples to secondary cups, pipette the sample carefully to avoid the introduction of air bubbles or foam.
3. Insert sample racks carefully to avoid disturbing the samples.

► Clots or particles in the sample

1. Re-centrifuge the sample, if necessary.
2. Alternatively, transfer some sample, free of clots or particles, into a secondary cup.

► Probes not clean

1. Perform the service action Deproteinize Probes.
2. Perform the service action Clean Probes Manually.
3. If this does not work, replace the probes.

► Leaking tubing or connections

Leaking tubing or connections in the fluid system may lead to pipetting errors.

“Leakage” on page E-30
“Air bubbles in one or more pipettes” on page E-31
“Dripping pipettes” on page E-31
“Dripping probes” on page E-32

► Evaporation or deterioration of the sample

1. Use fresh material, if possible.
2. If the sample is in a secondary cup, transfer a new aliquot to a new cup from the original primary sample.

► System water quality is unsuitable

1. Check the quality of the input water according to the instructions provided by the manufacturer of the deionized water supply system.
2. You must use reagent grade, type 1 water or equivalent.
3. If the water quality is not within specification, take the necessary action as recommended by the manufacturer of the deionized water supply system.

► Wash station is defective

1. Check for leakage on the bench under the wash station.
2. Check that the waste connector is properly connected and that the tubing is not clogged.
3. If any leaks persist, contact Roche Service.

“Leakage” on page E-30
“Air bubbles in one or more pipettes” on page E-31
“Dripping pipettes” on page E-31
“Dripping probes” on page E-32

Test results low or drifting

Results are obtained, but the values obtained are lower than expected.

Results are obtained, but the values show a consistent trend to drift (either up or down) from their expected values.

► Pipetting incorrect sample or reagent volumes

1 Perform the service action Deproteinize Probes.

2 Perform the service action Clean Probes Manually.

3 If this is unsuccessful:

  a. Replace the probes.

  b. Check the pipettes and pistons.

  c. Check for leaks.

"Leakage" on page E-30
"Air bubbles in one or more pipettes" on page E-31
"Dripping pipettes" on page E-31
"Dripping probes" on page E-32

► Sample has deteriorated

Sample has deteriorated, for example, due to instability of the analyte.

1 Use fresh material, if possible.

2 If the sample is in a secondary cup, transfer a new aliquot to a new cup from the original primary sample.

Hardware

This section lists problems associated with hardware functions, particularly regarding the cuvettes and the fluid system.

Reacting to a hardware message

► **To react to a hardware message**

1. Read the message and follow the instructions in the Help text to this message.
2. If this does not solve the problem click Stop.

   The Stop Actions dialog box is displayed.

   a. If you can continue processing orders, select Sampling Stop.

   b. If you cannot continue processing orders, select Stop.
3. Perform the Initialize System service action.
4. If this does not solve the problem, perform a system shutdown and restart the system.
5. If this does not solve the problem, contact Roche service.

"To react to a message" on page E-4
"(Re)Starting and stopping a run" on page B-37
"Re-initializing" on page E-13
"Shutting down the system" on page B-35
"Switching on the system" on page B-31
"Roche service" on page D-47

Cuvettes

Cuvettes must meet stringent optical specifications before they can be used on the instrument. Defective cuvettes are discarded automatically.

► **System discards a large number of unused cuvettes**

1. Remove several cuvettes from the reservoir.
2. Check whether they are cloudy, scratched, or dirty. If so, empty the cuvette reservoir manually and refill with new cuvettes.
3. If this is unsuccessful, open the analyzer cover and carefully remove some cuvettes from the cuvette buffer slide with tweezers. If these cuvettes are scratched or dirty, contact Roche Service.

Clot error after pipetting from sample cup

Pressure sensors are fitted to detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

► **The tube or cup indicated may contain clotted sample material. There will be no further pipetting from this cup.**

Make sure no clots are contained in the sample cup. Depending on the kind of specimen, centrifuging or filtering may solve the problem.

► **No sample pipetting possible due to previous sample cup clot error**

Remove the clot physically from the sample.

Clotted transfer

Pressure sensors are fitted to detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

► **Clot detection for the transfer arm. Attempting to resume operation.**

1. Look for other messages which may indicate the source of the clot.
2. If the next wash operation succeeds the system will continue to operate normally.

Clot error after sample/probe washing

Pressure sensors are fitted to detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

► **Extensive clots have been detected in a sample probe which could not be removed automatically. The system will be stopped and some scheduled tests may need to be repeated.**

1. Look for other messages which may indicate the source of the clot.
2. Wait until the system is in Standby.
3. Apply the cleaning procedure for the sample probe.
4. Check the onboard samples for clots.

"Clean probes and splash guard" on page D-24

Sample prime clot error

Pressure sensors are fitted to detect clots during aspiration of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

► **Extensive clots have been detected in a sample probe which could not be removed automatically. Therefore the system will not start measuring.**

1. Look for other messages which may indicate the source of the clot.
2. Wait until the system is in Standby.
3. Apply the cleaning procedure for the sample probe.

"Clean probes and splash guard" on page D-24

4. Check the onboard samples for clots.

Leakage

Fluid leaks can sometimes occur, especially when service actions (for example, Replace Dosage Pipette Plunger Tip) are not properly completed.

► **Leaking pipettes**

1. Check that the pipette is firmly screwed into place and tighten, if necessary (do not

over-tighten any connections).

2 If the leak is from the barrel of the pipette, replace the pipette or piston.

► Leaking tubing or tubing connections

1 Check that the tubing connectors are firmly screwed into place and tighten, if necessary (do not over-tighten any connections).

2 Check the external water and external waste tubes and ensure they are properly connected and not damaged.

3 Turn off the external water supply and reconnect or replace the water tubes, if necessary.

4 If the leakage is from the internal fluid system (on the instrument), perform a shutdown and switch off the system, then contact Roche Service.

Air bubbles in one or more pipettes

Air bubbles are a sign that the fluid system (most likely a pipette) is leaking or that the cleaner is running low or the water supply is not properly connected.

► Pipette not correctly installed

1 Reinstall the pipette or the piston ensuring no air bubbles are trapped.

2 Check for air bubbles appearing after reinstallation.

3 If air bubbles reappear, call Roche Service.

“Replace plunger tip dosage pipette B (or C)” on page D-57

► Water supply or cleaner not properly connected

1 In Status / Analyzer, check whether the cleaner is running low. If necessary, replace the cleaner.

2 Check the connections to the cleaner and water supply.

3 Perform the service action Prime the fluid system.

“Replacing the cleaner” on page B-43
“Waste, water, and power connectors” on page E-37
“Prime the fluid system” on page D-46

Dripping pipettes

If a visual inspection shows that either of the pipettes is leaking, you must take immediate action.

► Pipette not correctly installed

- Reinstall the pipette.

“Replace plunger tip dosage pipette B (or C)” on page D-57

► Piston worn out

1 Replace piston or pipette.

2 If the piston only is replaced and drips reappear after replacement, replace the

complete pipette.

👁 *“Replace plunger tip dosage pipette B (or C)” on page D-57*

Dripping probes

If a visual inspection shows that either of the probes is leaking, you must take immediate action.

► Loose tubing connections

1. Check that the tubing connectors are firmly screwed into place and tighten, if necessary (do not over-tighten any connections).
2. Replace the complete probe and tubing assembly, if necessary.

👁 *“Replace probe B (or C)” on page D-54*

► Damaged tubing or probe

- Replace the complete probe and tubing assembly, if necessary.

👁 *“Replace probe B (or C)” on page D-54*

► Valve is defective

A Hardware Warning message may be displayed (but not necessarily) stating that a valve is defective.

- Contact Roche Service.

► Damaged probes

1. Check the probes visually for damage and replace, if necessary.
2. Check whether there is any physical obstruction that might have damaged the probe, if so, remove the obstruction.

👁 *“Replace probe B (or C)” on page D-54*

► Due service actions not performed

Due service actions (related to pipettes and probes) were not performed on schedule.

- Use Service / All and perform all due service actions.

Temperature control

If the ambient temperature exceeds 30 °C, the refrigerant pressure becomes too high and the cooling system generates a hardware error.

1. Switch off the instrument at the main switch.
2. Ensure that at least one cassette slot is empty (to improve the air circulation inside the cooling box).
3. Switch on the main switch.
4. Allow the system to start up and complete its initialization.
5. Run the system with at least one spare cassette rack slot for about ten minutes.

After this, you can use all the slots for cassette racks.

6 If this does not fix the problem, contact Roche Service.

Software error messages

► The process <process name> is no longer responding

1 Click Shutdown in the message dialog box.

The *Cedex Bio HT* software is shut down and restarted.

2 Create a problem report.

👁 *“Creating a problem report” on page E-44*

For messages that are identified by an ID, see “Message Help” on page A-68.

Data station accessories

This section lists problems that may be associated with the data station, including connection problems, and other basic problems with the computer, monitor, printer, and barcode reader.

Connections

► Cables detached or damaged

1 Ensure that all the required connections are made.

"Connections check list" on page E-38

2 If any cables are damaged, contact Roche Service.

► Computer

1 Switch off the computer.
2 Insert the plugs in the correct sockets, press them in firmly.
3 Switch on the computer.

Monitor

► Screen is partially or completely black

1 Check that the monitor is plugged into the laboratory mains and that it is connected to the computer.
2 Check that the monitor is switched on (LED on the front right hand side).
3 Move the mouse or press a key to deactivate the screen saver.
4 Check the mains fuses.

"Replacing an instrument mains fuse" on page E-40

5 If this does not fix the problem, contact Roche Service.

► Screen is dim or dark

Check the screen brightness and contrast selections on the monitor, using the buttons below the screen.

Printer

► Printer connections and printer indicators OK, but still no printout

1 Check the printer settings in Windows XP.
2 Check that the printer driver, currently used as the default, corresponds to the printer actually connected. Modify the printer settings, if necessary.
3 Switch the printer off and back on again to re-initialize.
4 If printing is still not possible, shut down the system. Restart and wait until the

system is initialized.

"Shutting down the system" on page E-13
"Restart processing" on page E-13

5 If the problem reoccurs, contact Roche Service.

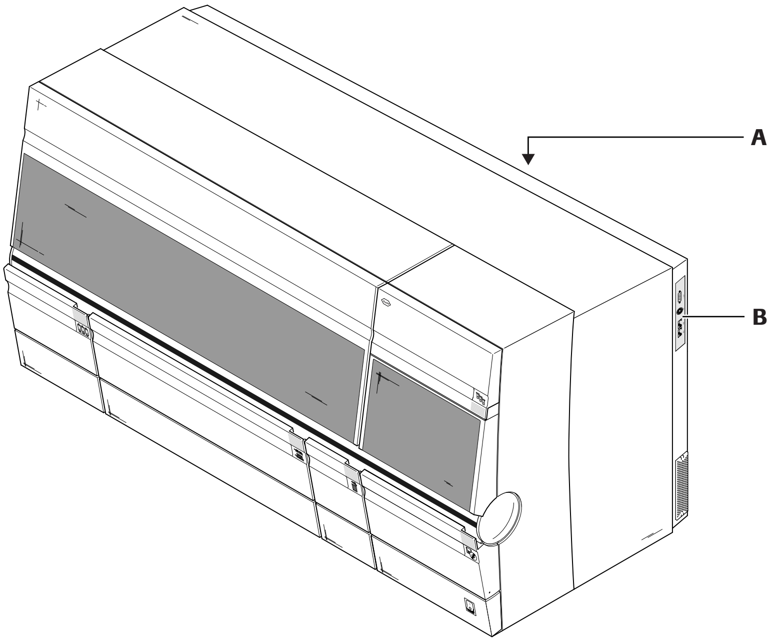
Barcode scanner

► Barcode scanner cannot read the barcodes

1. Check that the barcode scanner window is free of grease and dirt.
2. Clean the barcode scanner window, if necessary.
3. Check whether the barcode setup, including the reading of the installation barcodes, was properly completed.
4. Check whether the printing quality of the barcode labels is sufficient.
5. Check whether there is condensation on the barcode labels.

External connectors

The connectors that you may need to check are located either at the back of the instrument (A) or on the right side near the back (B) as shown below.

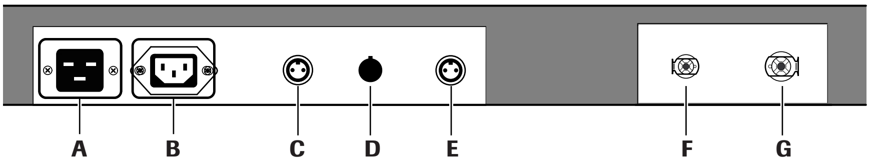


A *Waste, water, and power connectors (not visible here)*

B *Data connectors*

Waste, water, and power connectors

The waste, water, and power connectors are located at the back of instrument.



A *Mains input connector*

B *Mains supply, for example for optional printer.*

C *Water reservoir level sensor*

D *Not used*

E *Waste reservoir level sensor*

F *Water reservoir connector*

G *Waste reservoir connector*

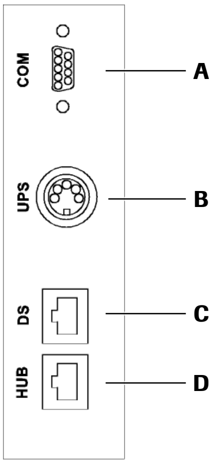
Tips

- Do not touch mains cables, if your hands are wet.

- Do not attempt to connect or disconnect either of the mains cables, if the instrument is switched on.
- If any power connector becomes worn or frayed, it must be replaced immediately with an approved cable. Contact your Roche Service representative.
- You must connect the waste sensor, if you are using a separate waste container (that is, the instrument is not connected to the main laboratory waste system).
- You must connect the water sensor, if you are using an external water reservoir.

Data connectors

These connectors are located on the right-hand side of the instrument near the back.



A *COM: Serial communications connector*

B *AUX: Auxiliary connector (not used)*

C *DS: LAN Direct connection to computer*

D *HUB: Not used*

Tip

Serial ports, if used, are configured by your Roche Service representative.

Connections check list

Use this list if you need to check that your system is properly connected.

Mains connections

- Check that the power cable of the computer is plugged in at both ends.
- Check that the power cable of the instrument is plugged in at both ends.
- Check that the power cable of the monitor is plugged in at both ends.

Connections between computer and instrument

- Check that the connection from the COM connector on the computer is made to the COM connector on the instrument.
- Check that the connection from the DS connector on the computer is made to the DS connector on the instrument.

Host connections

- If you work with a host system, check that the communication connection from the COM1 connector on the computer is made to the host computer.

Modem connection

- Check that the modem on the computer (Line) is not connected to the telephone socket. Do *not* use this connection for remote diagnostics.

2nd LAN connection

- This port can be used for remote diagnostics.

The 2nd LAN connector must only be used for Roche remote service connectivity. If a remote service connection is established over an unsecure network via an AXEDA client, the device must be installed behind either a Roche “connect 2” device or a cobas link gateway. The use of an AXEDA client is the only approved and supported remote service solution.

Warning

Other non-intended usage of the LAN connectors could lead to unauthorized database access resulting in possible disclosure or modification of sensitive data.

Monitor connections

- Check that the connection from the 15 pin VGA connector on the computer is made to the monitor.
- Check that the monitor power cable is plugged in at both ends.

Printer connections (optional)

- Check that the printer cable is connected from the LPT1 (25-pin) connector on the computer to the “Centronics” type connector on the printer itself.
- Check that the printer power cable is properly connected at both ends.

Barcode pen connections (optional)

- Check that the keyboard cable is connected to the female plug of the barcode pen.
- Check that the male plug of the barcode pen is firmly plugged in keyboard socket of the computer.

Handheld barcode scanner connection (optional)

- Check that the handheld barcode scanner is connected to an USB port.

Water supply

- Check that the water supply is connected. The instrument will not initialize properly if a water supply is not connected.
- Check that the water sensor is connected, if you are getting your water supply from a water container. (The water sensor must be inside the water container.)

Waste outlets

- Check that the waste outlet is connected to a suitable waste container or to a waste drain.
- Check that the waste level sensor is connected, if your waste is going to a waste container. (The waste level sensor itself must be inside the waste container.)

Checking and replacing fuses

A set of fuses protects the instrument from excessive electrical currents. If a fuse blows, a message is displayed to inform you that you need to replace that particular fuse.

How do I know whether a fuse has blown?

Typically, you get one or more messages from the appropriate controller informing you that the power to one or more subcomponents has failed. Also, the LEDs for the fuses for the controller boards are not lit when the fuse has blown (normally, they are bright green).

Where do I get the fuses from?

A complete set of replacement fuses is delivered in the start-up kit.

Why is the correct fuse important?

If you use a fuse that has too low a rating, it will almost certainly blow again. This wastes time, but is not in itself dangerous.

If you use a fuse that has too high a rating, your system will not be protected from excessive currents. This is very dangerous and can lead to a situation where a fire develops. Even without a fire you can get temperature control problems or other electrical faults if the underlying problem reoccurs.

Danger

Fire hazard!
For continued protection replace fuses only with fuses of the same type and rating.
Danger of electrocution!
Always disconnect the instrument from the mains before attempting to replace any fuse. Do not attempt to work with fuses if your hands are wet or if there is excess moisture on any fittings or components.

Replacing an instrument mains fuse

There are two mains fuses, both of which must have the same current rating, which depends on the mains voltage supplied to the instrument:

Mains voltage	Fuse rating
230 VAC / 200 VAC	8 A
115 VAC / 100 VAC	15 A

The mains input voltage is pre-selected by a jumper on the voltage selection unit.

To replace the fuse, you need the following tools and materials:

- Replacement fuses
- 4 mm screwdriver

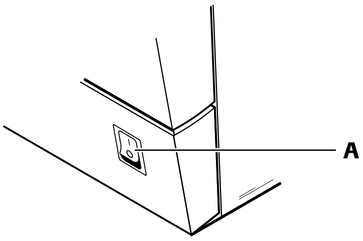
► To replace a mains fuse

1 Choose File > Shut Down.

Your are asked to confirm.

2 Switch off the computer

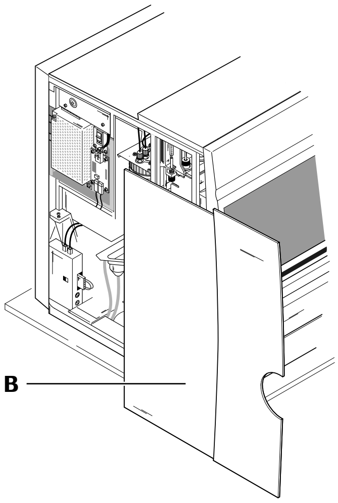
3 Switch off the instrument at the main switch (A).



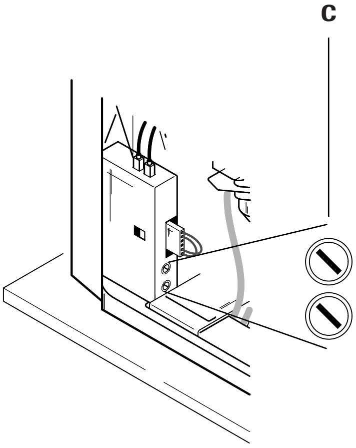
4 Isolate the instrument from the mains power supply by removing the power connector from the back of the instrument.

If you do not know how to do this, do not attempt this procedure!

5 When you are sure that the instrument is isolated from the mains power supply, remove the left side panel (B).



6 Locate the two mains fuses (C).



7 Using a small screwdriver, turn the fuse holder counter-clockwise.

The fuse is spring-loaded and pops out as you turn the fuse holder.

8 Place the new fuse into the fuse holder and re-insert.
9 Replace the left side panel (B).
10 Reconnect the instrument to the mains power supply.
11 Switch on the instrument at the main switch (A).
12 Switch on the computer.
13 If the fuse fails again, contact Roche Service.

Replacing the cooling unit fuse

The cooling unit fuse is located on the left side of the instrument, behind the left side panel. It has the following rating:

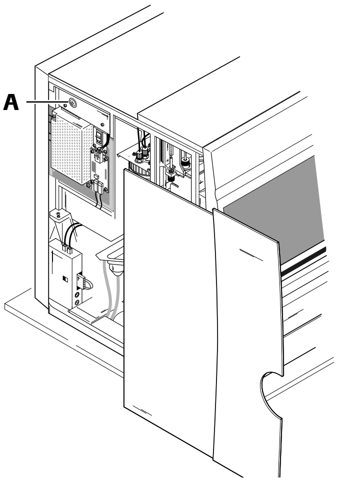
Voltage range	Fuse rating
100 - 125 VAC	T 8 A
200 - 240 VAC	T 4 A

To replace the fuse, you need the following tools and materials:

- Replacement fuse
- 4 mm screwdriver

► To replace the cooling unit fuse

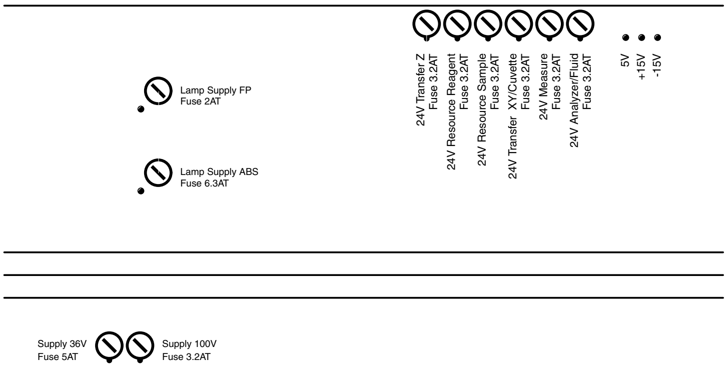
1 Follow the instructions “To replace a mains fuse” on page E-40 with exception of point 6. See below for the exact location of the cooling unit fuse (A).



Replacing controller board fuses

The controller board fuses protect the electronic controller circuit boards that are located under the main front cover. To see if a fuse has failed, check the LEDs (there is one for each fuse); a green LED means that the fuse is working.

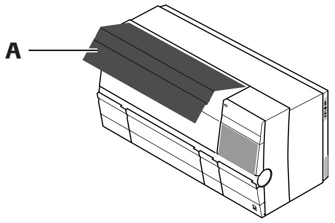
The layout of the controller board fuses is as follows:


Lamp Supply FP
Fuse 2AT
Lamp Supply ABS
Fuse 6.3AT
24V Transfer Z
Fuse 3.2AT
24V Resource Reagent
Fuse 3.2AT
24V Resource Sample
Fuse 3.2AT
24V Transfer XY/Cuvette
Fuse 3.2AT
24V Measure
Fuse 3.2AT
24V Analyzer/Fluid
Fuse 3.2AT
5V
+15V
-15V
Supply 36V
Fuse 5AT
Supply 100V
Fuse 3.2AT

► To replace a controller board fuse

1 Wait for the instrument to go into Standby.

2 Open the main front cover (A).



Caution

Main front cover

Danger of injury due to closing main front cover. If the main front cover is not opened completely it might close unintentionally by itself.
Whenever you open the main front cover, be sure to open it as far as it will go.

3 Identify the fuse(s) to replace (LED not lit). Make a note of the fuse type and rating, as shown next to the fuse.

4 Choose File > Shut Down.

Your are asked to confirm.

5 Switch off the computer

6 Switch off the instrument at the main switch.

7 Wait for the power down to complete.

8 Open the controller rack cover and, using a small screwdriver, turn the fuse holder counter-clockwise.

9 Replace the failed fuse with a fuse of the same type.

10 Re-insert the fuse.

11 Switch on the instrument at the main switch.

12 Switch on the computer.

13 If the problem occurs again, contact Roche Service.

Contacting Roche Service

Roche Service can help you solve many problems that you are unable to solve for yourself. However, before you contact Roche Service:

1. Check this chapter to see if your particular problem is described. If it is, follow the recommended procedures.
2. Search the online Help for the information you require. You can perform a full text search to help you find this information.
3. If this fails, contact your system supervisor for further advice.
4. If you still cannot solve the problem, make a note of any special conditions that you think might be relevant.
5. Create a problem report. (See “Creating a problem report” on page E-44.)
6. Contact Roche Service.

   In the first instance, contact the Roche remote diagnostics support service. This service allows a Roche service engineer to log on and control the system remotely. (See “Remote diagnostics” on page E-45.) For this level of support, a “connect 2” box or a cobas link gateway must be connected to the 2nd LAN port.

Creating a problem report

You can create a problem report by default on a floppy disk or alternatively on a USB Memory Stick. This report collates all the messages and other system information that the Roche Service engineers will need, if you cannot solve a particular problem on your own. You should create the report (if possible) before contacting Roche Service.

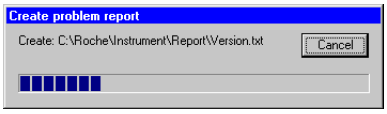
► To create a problem report on USB Memory Stick

1 Click Messages on the navigation bar.

2 Click the Options tab.

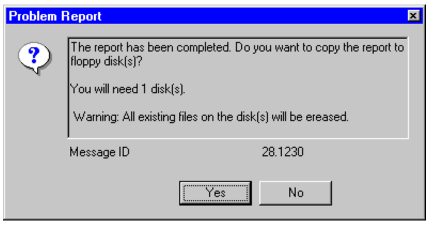
3 Click Report.

The Create Problem Report dialog is displayed.



Create: C:\Roche\Instrument\Report\Version.txt

4 When the report has been generated, the Problem Report dialog box is displayed again, telling you how many diskettes you need.



The report has been completed. Do you want to copy the report to floppy disk(s)?

You will need 1 disk(s).

Warning: All existing files on the disk(s) will be ereased.

Message ID 28.1230

5 Click No.

6 Insert a USB Memory Stick into a USB port of the computer of the *Cedex Bio HT* analyzer.

7 Press “Windows key” + E on the keyboard to open the Windows Explorer.

8 Open the folder C:\Roche\Instrument\Report\ZIP.

9 Copy the file PR.zip to your USB Memory Stick.

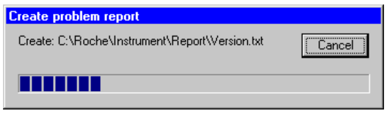
► To create a problem report on diskette

1 Click Messages on the navigation bar.

2 Click the Options tab.

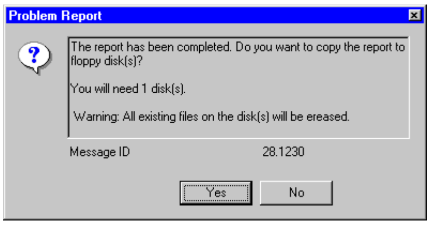
3 Click Report.

The Create Problem Report dialog is displayed.



Create: C:\Roche\Instrument\Report\Version.txt

4 When the report has been generated, the Problem Report dialog box is displayed, telling you how many diskettes you need.



The report has been completed. Do you want to copy the report to floppy disk(s)?

You will need 1 disk(s).

Warning: All existing files on the disk(s) will be ereased.

Message ID 28.1230

5 Insert a 3.5 inch diskette (any data on the diskette will be deleted).

6 Click Yes.

You can also create a problem report on diskette using the optional external Floppy Drive.

Tips

- You can also create a problem report from the message dialog box, for some types of messages.
- Contact your Roche contact person, and send the disk or the PR.zip file to your local Roche Service organization.
- If you turn off the main switch and turn on again, you may get a message prompting you to create a problem report before the system re-initializes. You can ignore this message.

Remote diagnostics

Use the Roche remote diagnostics support service whenever you have a problem that you cannot resolve.

This service allows a Roche Service engineer to log on and control the system remotely. For this level of support, a “connect 2” box or a cobas link gateway must be connected to the 2nd LAN port

► To enable a remote diagnostic session

1 Check that a “connect 2” box is connected to the 2nd LAN port.

“Data connectors” on page E-38
“Connections check list” on page E-38

2 Ensure that both the instrument and the computer are on. You do not have to be logged on; the Service engineer will automatically log on using AXEDA.

3 The Roche Service engineer can now access your system remotely.

Customer confidentiality

When a service engineer logs on to your system remotely, sample results are available on the remote system - as are records of calibrations, controls, and service actions.

A message will be displayed on your system, informing you that the system is currently accessed by remote access.

Make a note of the following information

When you report a problem to Roche Service, please have the following information available:

- Analyzer serial number
- Maintenance information (see service notes in the Service work area)
- System software version
- TAS version of the test in question
- TAS version installed on the system
- Description of the problem
- Description of the last operations (carried out immediately before the problem arose)

Problems with chemistry

For chemistry troubleshooting, you should also have the following additional information available:

Item	Lot number
Cassette	
Calibrator	
Control	
Diluent	

You may also need the following:

☐ The last calibration and control results
☐ A printout of the cassette status
☐ A printout of the raw data of the specific test(s)

ISE measurements F

Part F describes the operational principles of the ISE module and how to use it. It shows you step-by-step how to perform ISE service actions (routine maintenance procedures) and other related procedures.

The troubleshooting section suggests user actions to solve problems with ISE measurements.

ISE module

An overview of the ISE module

This chapter provides a description and general overview of the *Cedex Bio HT* ISE module. It describes the main components of the ISE module and how it operates. It also describes in general terms how to make ISE measurements and is supported by an ISE solutions summary.

In this chapter *Chapter* 17

Overview F-4
  Measuring modes F-4
  Parts of the ISE module F-5
  ISE rack F-7
How the ISE module works F-8
  Principles of operation F-8
  Calibrations F-9
  STAT orders F-9
  Electrode service F-9
  ISE Standby F-10
  ISE service actions F-10
Making ISE measurements F-11
ISE solutions summary F-12
Technical specifications F-13

Overview

The ISE module is a measurement system for electrolytes that runs independently of the fluorescence polarization (FP) and absorbance photometry systems. The ISE module uses the same samples, racks, and tubes that are used for photometric measurements, and the samples are transferred using probe C. The ISE module also uses specific solutions, some of which are kept in bottles on the ISE rack, the others on the ISE module itself.

Measuring modes

The *Cedex Bio HT* ISE module serves for quantitative determination of the following electrolytes:

- Sodium
- Potassium
- Chloride (optionally)
- Lithium (optionally)

There are two measuring modes:

Measuring mode	Description
Direct mode	The sample, control, and standard solutions are used undiluted.
Indirect mode	The sample, control, and standard solutions are diluted with system water.

The dilutions and the mixing are performed automatically in the ISE tower.

The tests available in each mode are as follows:

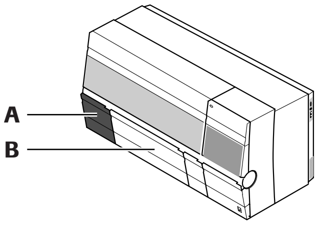
	ISE Direct	ISE Indirect
Sodium	✓	✓
Potassium	✓	✓
Chloride	✓	✓
Lithium	✓	✗

✓ = available, ✗ = not available

ISE measurements ISE measurements and photometric measurements are carried out at the same time and are independent of each other (ISE measurements do not use cuvettes, the analyzer rotor, or photometers). In addition, all requested ISE measurements on a specific sample (or calibrator) are performed in parallel, that is, measurements are made at each electrode at the same time.

Parts of the ISE module

The ISE module is located behind the ISE access panel. The ISE rack (see page F-6) is on the sample rack platform.



A *ISE access panel*

B *ISE rack accessed through the rack area panel*

The following figure shows the main parts of the ISE module:

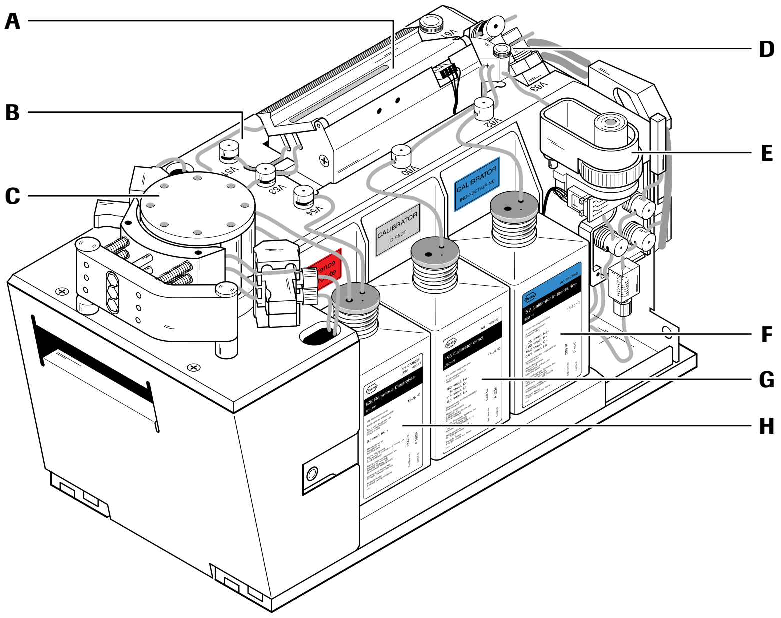


Figure C-1 Main features of the ISE module

A *Electrode block*

B *ISE module tubing*

C *Peristaltic pump*

D *Distribution block*

E *ISE tower*

F *ISE Calibrator Indirect*

G *ISE Calibrator Direct*

H *ISE Reference Electrolyte*

The main parts of the ISE module are as follows:

ISE module part	Description
Electrode block	A metal block that contains the electrodes shielding them from electromagnetic interference.
Peristaltic pump	A fluid pump that draws the solutions through the electrode block and then into the sample waste.
ISE tower	A hollow, transparent cylinder with multiple inlets and outlets for air and solutions. When the ISE tower is blocked, the user can remove and clean it. In the ISE tower, samples and diluents for indirect measurements are mixed using an air stream. (Undiluted samples are not mixed.)
Tubing (not shown)	Tubing is used to connect the ISE module with the water and waste system. Tubing is also used for sample waste, ISE Reference Electrolyte, and ISE calibrators, which are contained in bottles on the ISE module.
Sample transfer arm (not shown)	The sample transfer arm uses probe C to pipette samples into the ISE tower. If required, samples may be diluted automatically.
Valves (not shown)	A set of valves controls the flow of liquids through the tubing.
Sensors	A pair of sensors detects the presence of liquid or air and enables the correct placing of segments for measurement and cleaning.
ISE distribution block	A transparent plastic block used for liquid and air distribution within the ISE module.

ISE solutions on the module

The following ISE solutions are stored in bottles that are located on the ISE module itself:

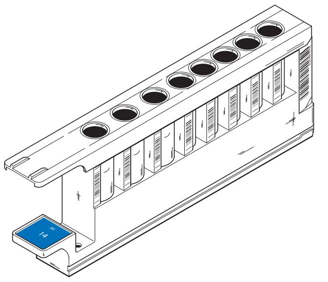
- ISE Reference Electrolyte Bio HT
- ISE Calibrator Direct Bio HT
- ISE Calibrator Indirect Bio HT

👁 *"Replace bottles on ISE module" on page F-34*

ISE rack

The ISE module uses a special rack called the ISE rack which is always loaded into slot O to the right of the sample platform.

The ISE rack contains the ISE solutions essential for its operation. You must place each solution in its correct position as defined in Configuration / System / Lab / Reserve Positions. The Activator and ISE Deproteinizer in particular, need to be placed in the correct positions as the service action Clean / Deproteinize probes cannot be performed.



You are recommended not to change the default configuration unless this is essential. In this manual, all references to the ISE rack assume the default configuration.

You can review the status of solutions on the ISE rack by clicking the ISE tab in the Status work area.

“Replace ISE solutions on the ISE rack” on page F-32

The ISE rack must contain ISE Deproteinizer and Activator. You can also use the ISE rack for solutions such as cleaners and diluents.

How the ISE module works

The electrolyte module uses flow-through ion-selective electrodes and a reference electrode with an open liquid junction. Each electrode has a membrane or capillary that is sensitive to a particular type of ion.

Principles of operation

1. The sample is pipetted from the sample tube (located on a sample rack) into the ISE tower. Depending on the pipetting mode, the sample is diluted with system water. Mixing is performed with four air jets arranged in a circle. These jets blow air into the tower to produce a homogenous mixture.
2. The other ISE solutions (ISE solution 1-3, ISE Deproteinizer, ISE Etcher, and Activator) are pipetted from the ISE rack into the ISE tower by the sample probe C, when required.
3. The sample is divided into segments with the aid of a special arrangement of valves. The first (shorter) segments are used for cleaning, followed by a longer segment, on which the measurements are made.
4. The sample is passed to the ion-selective electrodes by the action of the peristaltic pump.
5. The exact positioning of segments is ensured by fluid sensor 2 in the measuring channel.
6. In the meantime, the ISE tower is washed with distilled water and dried.
7. ISE Reference Electrolyte is passed through the reference electrode and into the measuring channel downstream of the electrodes. The ISE Reference Electrolyte completes the electrical circuits for each electrode so that measurements can be made. When the measurements are made, the sample and ISE Reference Electrolyte are stationary.
8. A one-point calibration is performed after each sample measurement using the relevant calibrator, which is located on the right side of the ISE module.
9. The electrolyte concentration of the sample is calculated.
10. The measuring channel is cleaned before the next measurement.

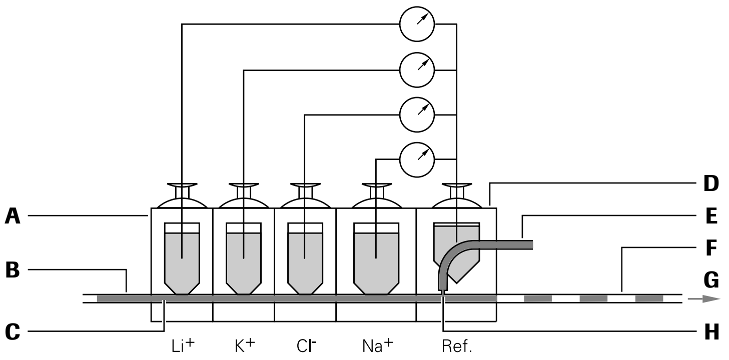


Figure C-2 Principal parts of the ISE measurement system

A *Ion-selective electrode*
B *Samples, controls, calibrators, Activator, ISE Etcher, and ISE Deproteinizer*
C *Measuring channel*
D *Reference electrode*
E *ISE Reference Electrolyte*
F *Air segments*
G *Waste*
H *Liquid junction*

Determination of lithium

The lithium electrode is not exclusively sensitive to lithium ions alone. Sodium ions and, to a lesser extent, potassium ions, also contribute to the measured signal. These contributions are determined for each lithium measurement and each lithium result is corrected accordingly. Therefore, to make lithium determinations, you must have both the sodium and potassium electrodes installed and working.

Calibrations

The ISE module requires frequent calibration to ensure the reliability of the test results obtained. All the required calibrations are performed automatically, although you can request a main calibration at any time.

Main calibration

Sodium, potassium, and chloride, are calibrated with a two-point calibration (duration 126 seconds) using ISE solutions 1 and 2. Lithium is calibrated with a three-point calibration (duration 168 seconds) at fixed intervals using ISE solutions 1, 2, and 3. The time interval for main calibrations is five hours.

One-point calibration

The ISE module automatically performs a one-point calibration with the corresponding ISE calibrator, depending on the measuring mode. For example, in direct mode, the ISE Calibrator Direct is used for the one-point calibration.

One-point calibrations are performed within the ISE cycle of 53 seconds.

Measuring modes

All ISE measurements are made in one of two measuring modes:

- Measuring direct
- Measuring indirect

In addition, the electrodes are calibrated at regular intervals and recalibrated after each measurement.

You cannot switch between measuring modes manually; this is always automatic.

STAT orders

ISE STAT samples are pipetted before routine samples.

Electrode service

Electrode Service is a service action that is automatically performed at Begin of Day (BOD) and during each electrode replacement. While Electrode service is taking place, the ISE module cannot carry out any tests.

An Electrode service contains the following steps:

- The electrodes are cleaned with ISE Deproteinizer to prevent protein build up on the electrodes and in the tubing.
- The surface of the sodium electrode is conditioned by etching.
- Electrodes are activated with Activator. The Activator is pipetted into the ISE tower and drawn through the measuring channel.

Chapter 18, "ISE service actions"

ISE Standby

If there is no measurement after three minutes, the ISE module switches to Standby state. ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes. ISE Calibrator Direct, and ISE Reference Electrolyte are primed through the ISE module at fixed intervals (every two hours).

ISE Standby helps to prevent the following problems:

- Overflow of ISE Reference Electrolyte backwards into the measuring channel, which can damage the electrodes because of the high ion concentration of the ISE Reference Electrolyte.
- Crystallization of salts in the tubing (blockage).

ISE service actions

The service of the ISE module is supported by online service software. The software guides you through the service procedures to be performed at fixed time intervals or at other times depending on the work load. User defined service actions can be defined to be performed automatically by the system during the Begin of Day (BOD) procedure.

Chapter 18, "ISE service actions"
"Technical specifications" on page H-4

Making ISE measurements

The ISE module is a fully integrated part of the *Cedex Bio HT* system. You make requests for orders and place samples in the same way that you do for other types of tests. However, you must ensure that the ISE solutions and auxiliary reagents are in their correct positions.

► To make ISE measurements

1 Check the positions of solutions and reagents on the ISE rack.

a. If necessary, remove the ISE rack. Wait until the ISE-rack LED on the rack status panel is green before removing the rack.

b. Confirm that the ISE solutions and auxiliary reagents (cleaners, diluents) are in their correct positions on the ISE rack.

👁 *"ISE solutions summary" on page F-12*

2 Ensure that all the bottle caps (except for the Activator, which has no cap) are closed firmly.

👁 *"Replace bottles on ISE module" on page F-34*

3 Check that the ISE calibrators and ISE Reference Electrolyte are in their correct positions

👁 *"Replace bottles on ISE module" on page F-34*

⚠ **Caution**

ISE Reference Electrolyte Bio HT
The ISE Reference Electrolyte Bio HT is not a calibrator and it should not be used as such. The ISE Reference Electrolyte is automatically used with the reference electrode (and only the reference electrode) to make the electrical circuit with the measuring electrodes. Using the ISE Reference Electrolyte Bio HT as a calibrator or a sample will damage the electrodes.

---

4 Create an order.

Create an order for ISE tests in the Orders work area in the same way as other tests are ordered.

ISE tests are multi-tests, in that all ordered ISE tests for one sample are performed simultaneously with one sample pipetting.

👁 *"Creating an order" on page B-95*

5 Load samples.

Place your sample in any convenient position on a sample rack, just as you would with any other test (barcoded samples) or use the Place Items dialog box (Tools / Place Items).

👁 *"Loading samples" on page B-38*

6 Check results.

The results are displayed in the same way as any other results.

👁 *"Working with results" on page B-128*

ISE solutions summary

Solution	Cap	Location	Position	Usage
ISE Solution 1	Yes	ISE rack	6	Two-point calibration of sodium, chloride, and potassium and for the three-point calibration of lithium. Also used for the initialization of the ISE module.
ISE Solution 2	Yes	ISE rack	5	Two-point calibration of sodium, chloride, and potassium and for the three-point calibration of lithium.
ISE Solution 3	Yes	ISE rack	4	Three-point calibration of lithium only.
ISE Calibrator Direct		ISE module		One-point calibration after each ISE direct measurement, which is performed once every ISE cycle when the module is in ISE direct mode. Also used during ISE standby and for servicing purposes.
ISE Calibrator Indirect		ISE module		One-point indirect ISE calibration, which is performed once every ISE cycle.
ISE Reference Electrolyte		ISE module		Used in all ISE measurements of sodium, potassium, chloride, and lithium.
ISE Etcher	Yes	ISE rack	3	A cleaning solution intended for use with the ISE module for cleaning the sodium electrode during ISE service.
ISE Deproteinizer	Yes	ISE rack	8	A cleaning solution intended for use with the ISE module for cleaning the probes during BOD, the ion-selective electrodes, ISE tower, and tubing during ISE service.
Activator	No	ISE rack	2	Activates the electrodes in ISE service actions and is also used for the initialization of the ISE module and for BOD.

Caution

Roche recommends to use the Roche Activator for Cedex Bio HT systems as ISE Activator.

Use only the Activator Bottle set for Cedex Bio HT systems which contains the appropriate 11 mL plastic bottles.

For further details refer to the Activator for Cedex Bio HT systems package insert.

Confirm replacement for bottles that have been interchanged on the ISE rack. Prior to this, you have to change the rack positions for the ISE solutions and/or diluents. Use Configuration / Lab / Reserve Positions.

Technical specifications

“Technical specifications” on page H-4

ISE service actions

Maintenance tasks for the ISE module

This chapter describes the service actions and maintenance tasks for the ISE module. It provides step-by-step procedures to guide you through the service actions. It lists the potential hazards and precautions in each case.

General maintenance procedures related to the ISE module are also described.

In this chapter

Chapter **18**

About ISE service actions F-16
    General safety precautions F-16
    Automatic service actions F-16
Initialize ISE module F-17
Electrode service F-18
Activate electrodes F-19
Prime ISE calibrators F-20
Clean ISE tower automatically F-21
Clean ISE tower manually F-22
Replace ISE module tubing F-25
Replace electrode F-27
Condition ISE tubing F-31
Replace ISE solutions on the ISE rack F-32
Replace bottles on ISE module F-34
Replace ISE tower F-36
ISE Performance Check F-37

About ISE service actions

ISE service actions work in the same way as the non-ISE service actions and are listed in the Service work area where you start them in the same way. ISE service actions also use the same type of service action dialog boxes, to help guide you through the steps you need to take.

Some of the service actions do not need manuel interaction. From those you can choose a set to run automatically at the beginning of day (BOD)

Chapter 13, "Service action software"

You can click Help in the Service Actions dialog box for online information for each service action.

General safety precautions

Danger

Before removing main cover disconnect mains plug from socket. Hazardous voltage is present on ISE power supply even if main switch is off. Danger of electric shock when touching power supply components.

Caution

Read and understand the Roche safety precautions at the beginning of this manual and the hazards and precautions contained in this chapter. This information should be made available to all employees and kept for further reference.
Users must not perform any servicing except as explicitly described in this manual.

Automatic service actions

Automatic ISE service actions do not require any specific precautions; however, you should always observe the following warnings:

Hazards

- The ISE module, including the tower, fluid waste, tubing, and electrodes, is potentially infectious.
- Sample material is potentially infectious.
- There is a danger of cauterization and poisoning through skin contact with the reagents.

Precautions

- Make sure you read all the warning labels on the cassettes.
- Use protective gloves to avoid direct contact with sample material.
- Remove any spillage of sample material immediately.

Initialize ISE module

Overview

This is an automatic service action that does not require manual intervention.

The ISE module must be initialized at regular intervals to ensure proper transportation of fluids through the ISE module tubing.

The ISE module is automatically initialized during the Service action Replace ISE module tubing.

Duration 6 minutes

Interval Daily (can be assigned to BOD)

Begin of Day Yes

System state Standby

Tools and materials

- Activator
- ISE Calibrator Direct Bio HT
- ISE Reference Electrolyte Bio HT
- ISE Solution 1

Hazards and precautions See “General safety precautions” on page F-16.

► To initialize the ISE module

1. Select Initialize ISE module in the Service work area.
2. Click Perform.
3. Fluid system is initialized, if necessary [automatic step].
4. Transfer arm is initialized, if necessary [automatic step].
5. ISE Solution 1 is pipetted into the tower [automatic step].
6. ISE Solution 1 is transported to the fluid sensors [automatic step].
7. Probe C pipettes Activator into the ISE tower [automatic step].
8. The pipetted Activator is drawn into the electrode block [automatic step].
9. Steps 7 and 8 are repeated five times.
10. The ISE tower is washed and dried [automatic step].
11. ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.

Electrode service

Overview	*This is an automatic service action that does not require manual intervention.* The electrodes must be cleaned regularly to prevent the build up of deposits to maintain the efficiency of the instrument. This service action includes etching, deproteinizing and tubing conditioning steps.
Duration	8 minutes
Interval	• Daily, or • Every 3 days if less than 50 samples per day are processed
Begin of Day	Yes
System state	Standby
Tools and materials	• Activator • ISE Calibrator Direct Bio HT • ISE Deproteinizer Bio HT • ISE Etcher Bio HT • ISE Reference Electrolyte Bio HT
Hazards and precautions	See “General safety precautions” on page F-16.

► **To service electrodes**

1. Select Electrode service in the Service work area.
2. Click Perform.
3. Fluid system is initialized, if necessary [automatic step].
4. Transfer arm is initialized, if necessary [automatic step].
5. ISE module is initialized, if necessary [automatic step].
6. Electrodes are deproteinized [automatic step].
7. Electrodes are etched [automatic step].
8. ISE module tubing is conditioned twice with Activator [automatic step].
9. Electrodes are rinsed with ISE calibrator [automatic step].
10. Electrodes are activated twice with Activator [automatic step].
11. ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.

A calibration is run before any new samples or controls are processed [automatic step].

Activate electrodes

Overview	*This is an automatic service action that does not require manual intervention.* The electrode surfaces must be activated with Activator so that the correct potentials are measured.
Duration	3 minutes
Interval	• After every 50 measurements, or • Daily if less than 50 samples per day are processed
Begin of Day	Yes
System state	Standby or Operating. You can perform this service action at the same time as absorbance and FP measurements are made.
Tools and materials	• Activator • ISE Calibrator Direct Bio HT • ISE Reference Electrolyte Bio HT
Hazards and precautions	See “General safety precautions” on page F-16.

► To activate electrodes

1. Select Activate electrodes in the Service work area.
2. Click Perform.
3. Fluid system is initialized, if necessary [automatic step].
4. Transfer arm is initialized, if necessary [automatic step].
5. ISE module is initialized, if necessary [automatic step].
6. Probe C pipettes Activator into the ISE tower [automatic step].
7. The pipetted Activator is drawn into the electrode block [automatic step].
    - If the ISE module is in Standby, the Activator remains in the electrode block for 1 minute [automatic step].
    - If the ISE module is in Operating, the Activator remains in the electrode block for 40 seconds [automatic step].
8. Steps 6 and 7 are repeated twice [automatic step], if the ISE module is in Standby. If the ISE module is in Operating steps 6 and 7 are repeated three times.
9. ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.

Prime ISE calibrators

Overview

This is an automatic service action that does not require manual intervention.

You must prime the ISE calibrators when you replace a bottle containing ISE calibrator or ISE Reference Electrolyte. This ensures that no traces of a previous calibrator are left in the tubing and therefore prevents drift in the results.

Warning

Results produced with fresh calibrator bottles are not reliable unless you perform the service action Prime ISE calibrators.

Duration	1 minute
Interval	Daily
Begin of Day	Yes
System state	You can perform this procedure at the same time as absorbance and FP measurements are made (Operating).
Tools and materials	• ISE Calibrator Direct Bio HT • ISE Calibrator Indirect Bio HT • ISE Reference Electrolyte Bio HT
Hazards and precautions	See “General safety precautions” on page F-16.

► **To prime ISE calibrators**

1. Select Prime ISE calibrators in the Service work area.
2. Click Perform.
3. Fluid system is initialized, if necessary [automatic step].
4. Transfer arm is initialized, if necessary [automatic step].
5. ISE module is initialized, if necessary [automatic step].
6. ISE Calibrator Direct, ISE Calibrator Indirect, and ISE Reference Electrolyte are pumped through the ISE module tubing [automatic step].
7. ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.

A calibration is run before any new samples or controls are processed [automatic step].

Clean ISE tower automatically

Overview	*This is an automatic service action that does not require manual intervention.* The ISE tower must be cleaned regularly to ensure the proper functioning of the ISE module.
Duration	11 minutes
Interval	• Weekly • Daily if more than 50 plasma samples are processed per day
Begin of Day	Yes
System state	Standby
Tools and materials	• Activator • ISE Calibrator Direct Bio HT • ISE Deproteinizer Bio HT • ISE Reference Electrolyte Bio HT
Hazards and precautions	See “General safety precautions” on page F-16.

► To clean the ISE tower automatically

1 Select Clean ISE tower automatically in the Service work area.

2 Click Perform.

The Service Actions dialog box is displayed; follow the online prompts as required.

3 Transfer arm is initialized, if necessary [automatic step].

4 Fluid system is initialized, if necessary [automatic step].

5 ISE module is initialized, if necessary [automatic step].

6 ISE Deproteinizer is pipetted into the ISE tower [automatic step].

7 The pipetted ISE Deproteinizer is drawn through the tubing [automatic step].

8 Steps 6 and 7 are repeated three times.

9 The ISE tower and tubing are rinsed with system water [automatic step].

10 ISE module tubing is conditioned twice with Activator [automatic step].

11 Electrodes are rinsed with ISE Calibrator Direct [automatic step].

12 Electrodes are activated twice with Activator [automatic step].

13 ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.

Clean ISE tower manually

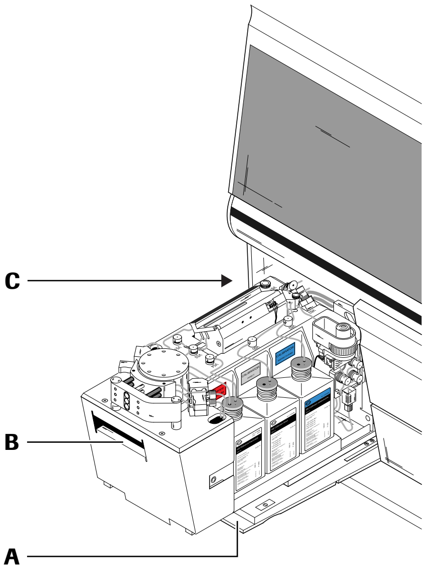
Overview	You must clean the ISE tower manually to ensure the proper functioning of the ISE module. The tower must be exchanged if it is blocked.
Duration	6 minutes
Interval	Every 30 days
Begin of Day	No
System state	Standby
Tools and materials	• Activator • ISE Calibrator Direct Bio HT • ISE Deproteinizer Bio HT • ISE Reference Electrolyte Bio HT • Cotton swab • Deionized water • Protective gloves • Small glass beaker
Hazards	• The ISE module, including the tower, fluid waste, tubing, and electrodes, is potentially infectious. • Sample material is potentially infectious. • There is a danger of cauterization and poisoning through skin contact with the reagents.
Precautions	• Do not perform this procedure if there are any ISE tests, calibrations, or service procedures running or pending. If you remove the ISE module in these circumstances, you may damage the instrument. • Make sure you read all the warning labels on the cassettes. • Use protective gloves to avoid direct contact with sample material. • Remove any spillage of sample material immediately.

► To clean the ISE tower manually

1. Select Clean ISE tower manually in the Service work area.
2. Click Perform.

   The Service Actions dialog box is displayed. Follow the online prompts as required.

3 Open the ISE access panel (A).



4 Pull out the ISE module using the handle (B).

You have to pull quite hard because the ISE module is lodged firmly inside its housing.

Pull the module out until the spring catch (C - attached to the rear of the module) is engaged.

5 Remove the ISE overflow collector (D) by pulling it upwards and rotating it from side to side as you do so.

6 Carefully remove the tubing from the base of the ISE tower (E).

7 Remove the locking bolt (F) from the base of the ISE tower by rotating it counter-clockwise one quarter of a turn and lifting it over the ISE tower (E).

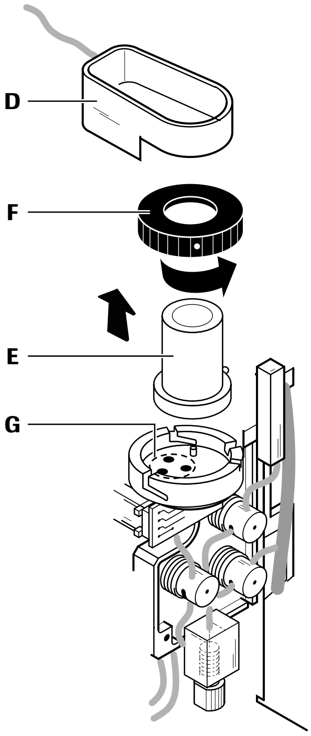
8 Remove the ISE tower (E).

(You can exchange the ISE tower at this point, if it is badly blocked.)

9 Clean the inside of the ISE tower with a cotton swab to remove any visible clots.

10 Soak the ISE tower in ISE Deproteinizer for about 5 minutes. (Extend the soaking time to 30 minutes if there are any clots in the ISE tower.)

11 Rinse the ISE tower in deionized water and leave



to dry.

12 Reinstall the ISE tower.

Ensure that all three sealing rings (G) between the ISE tower and the mounting are positioned correctly.

13 Reinstall the tubing.

Ensure that the tubing is placed in the corresponding tubing guide.

14 Reinstall the locking bolt and the overflow collector.

15 Release the spring catch and slide the ISE module back until it clicks into place.

16 Click next.

17 Electrodes are activated twice with Activator [automatic step].

18 ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.

19 When all steps are complete, click Finish in the Service work area.

Tips

- You must connect the tubing to the ISE tower correctly otherwise it may be damaged during initialization.
- If you replace one or more sealing rings, you must ensure that the replacements are exactly the same type as the originals.

Replace ISE module tubing

Overview The tubing must be replaced according to the ISE service action schedule. This ensures proper functioning of the ISE module.

Duration 38 minutes

Interval Every 180 days

Begin of Day No

System state Standby

Tools and materials

- Activator
- ISE Calibrator Direct Bio HT
- ISE Calibrator Indirect Bio HT
- ISE module tubing set
- ISE Reference Electrolyte Bio HT
- ISE Solution 1
- Protective gloves

Hazards

- The ISE module, including the tower, fluid waste, tubing, and electrodes, is potentially infectious.
- Sample material is potentially infectious.
- There is a danger of cauterization and poisoning through skin contact with the reagents.

Precautions

- Make sure you read all the warning labels on the cassettes.
- Use protective gloves to avoid direct contact with sample material.
- Remove any spillage of sample material immediately.

Warning

You must use the correct length of tubing as indicated in the tubing set. Using the incorrect length will ultimately result in a malfunction of the ISE module.
Use the service action Replace ISE module tubing in the Service program. Otherwise no ISE initialization is carried out.

► To replace ISE module tubing

1 Select Replace ISE module tubing in the Service work area.

2 Click Perform.

The Service Actions dialog box is displayed; follow the online prompts as required.

3 Transfer arm is initialized, if necessary [automatic step].

4 Fluid system is initialized, if necessary [automatic step].

5 ISE module is initialized, if necessary [automatic step].

6 Preparing ISE module for tube replacement [automatic step].

7 Refer to the cover of the tubing set to identify the correct tubing locations on the ISE module.

8 Replace the tubing.

9. ISE calibrators are primed [automatic step].
10. ISE module tubing is conditioned twelve times with Activator [automatic step].
11. ISE module is initialized [automatic step].
12. ISE wash time is detected four times with Activator.
13. ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.
14. When all steps are complete, click Finish in the Service work area.

Replace electrode

Overview

You must replace electrodes when their expiration date is exceeded or when the ISE results deteriorate despite regular service.

There are up to four ion-selective electrodes and a reference electrode on the ISE module. The replacement procedure is the same for each.

During replacing electrodes on the ISE module, the system performs automatically the “Electrode service” service action. This insures the proper functioning of the electrodes.

Duration

13 minutes per electrode

Interval

- Every 90 days for orange labeled chloride electrodes
- Every 14 days or 2000 counts for purple labeled chloride electrodes (Gen.2 electrodes)
- Every 120 days for lithium
- Every 180 days for sodium and potassium
- Every 720 days for the reference electrode

Begin of Day

No

System state

Standby

Tools and materials

- Activator
- ISE Deproteinizer Bio HT
- ISE Etcher Bio HT
- ISE Calibrator Direct Bio HT
- ISE Calibrator Indirect Bio HT
- ISE Reference Electrolyte Bio HT
- Chloride electrode (optional)
- Lithium electrode (optional)
- Potassium electrode
- Reference electrode
- Sodium electrode
- Protective gloves

Hazards

- The ISE module, including the tower, fluid waste, tubing, and electrodes, is potentially infectious.
- Sample material is potentially infectious.
- There is a danger of cauterization and poisoning through skin contact with the reagents.

Precautions

- Make sure you read all the warning labels on the cassettes.
- Use protective gloves to avoid direct contact with sample material.

- Remove any spillage of sample material immediately.

Warning

Before replacing the reference electrode, shorten both tygon tubings of the new reference electrode to a maximum length of 5 cm.

► To replace an electrode

1 Select Replace electrode in the Service work area.

2 Click Perform.

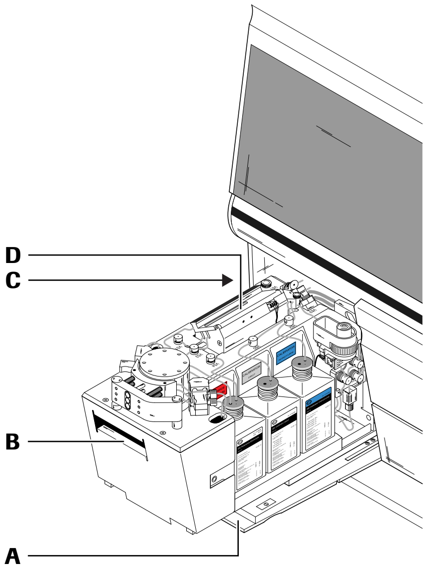
The Service Actions dialog box is displayed; follow the online prompts as required.

3 The electrodes are rinsed with ISE Calibrator Direct to remove any sample residue [automatic step].

4 Air is drawn into the ISE tower to empty the measuring channel [automatic step].

5 ISE Reference Electrolyte is drawn through the bypass [automatic step].

6 Open the ISE access panel (A).



7 Pull out the ISE module using the handle (B).

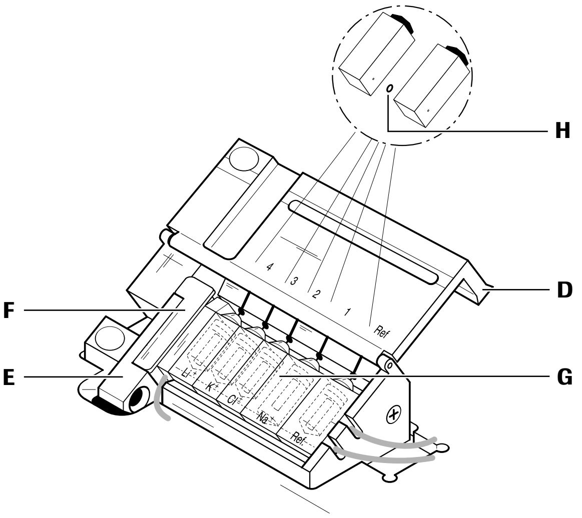
You have to pull quite hard because the ISE module is lodged firmly inside its housing.

Pull the module out until the spring catch (C - attached to the rear of the module) is engaged.

8 Remove the connector from fluid sensor 2.

9 Open the electrode block cover (D).

10 Remove the black cover for fluid sensor 2 (E).



11 Remove fluid sensor 2 (F).

12 Note the positions of the electrodes. You must replace them in the same positions.

13 Remove all the electrodes.

Warning

Before replacing the reference electrode, shorten both tygon tubings of the new reference electrode to a maximum length of 5 cm.

14 Replace electrodes as required.

Make sure that the electrodes (G) are reinstalled in their original positions.

Ensure that the electrodes and the electrode block are dry.

15 Take care not to lose the sealing O-rings (H):

- Between the electrodes.
- Between the fluid sensor and the adjacent.

You must use the correct type of sealing O-ring otherwise the ISE module will not run reliably.

16 Reinstall fluid sensor 2 and its cover.

17 Close the electrode block cover (D).

18 Reinstall the connector to fluid sensor 2.

19 Release the spring catch and slide the ISE module back until it clicks into place.

20 Click next.

21 ISE calibrators are primed [automatic step].

22 The ISE module is checked for leakage [automatic step].

23 If a leak is found, a message is displayed and you must check that all the connections in the ISE module are secure.

The following steps are performed:

- Fluid system is initialized, if necessary [automatic step].
- Transfer arm is initialized, if necessary [automatic step].

- ISE module is initialized, if necessary [automatic step].
- Electrodes are deproteinized [automatic step].
- Electrodes are etched [automatic step].
- ISE module tubing is conditioned twice with Activator [automatic step].
- Electrodes are rinsed with ISE calibrator [automatic step].
- Electrodes are activated twice with Activator [automatic step].
- ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.

24 When prompted:

   a. Indicate which electrode you have replaced.

   b. Click next.

   c. Specify the lot number of the new electrode.

25 When all steps are complete, click Finish in the Service work area.

A calibration is run before any new samples or controls are processed [automatic step].

Condition ISE tubing

Overview	*This is an automatic service action that does not require manual intervention.* When ISE module tubing has been replaced, it must then be conditioned to ensure the ISE module runs correctly.
Duration	3 minutes
Interval	None
Begin of Day	No
System state	Standby
Tools and materials	• Activator • ISE Calibrator Direct Bio HT • ISE Reference Electrolyte Bio HT
Hazards and precautions	See “General safety precautions” on page F-16.

► To condition tubing

1 Select Condition ISE tubing in the Service work area.
2 Click Perform.
3 Probe C pipettes Activator into the ISE tower [automatic step].
4 ISE module tubing is filled with Activator [automatic step].
5 Activator is transported to the fluid waste [automatic step].
6 Steps 3, 4, and 5 are repeated twelve times.
7 ISE Calibrator Direct is pumped into the measuring channel and transported slowly through the system every three minutes.

Replace ISE solutions on the ISE rack

Overview

This is a general procedure, not a service action.

The ISE tab in the Status work area gives information about the status of the solutions on the ISE rack. They must be replaced before the bottle is empty or as soon as the expiration date is reached.

Tools and materials

- Activator
- ISE Deproteinizer Bio HT
- ISE Etcher Bio HT
- ISE Solutions 1, 2, and 3 (3 only for lithium electrode)
- Protective gloves

Hazards

- There is danger of cauterization and poisoning through skin contact with the reagents.
- ISE Solutions 1, 2, and 3 must be replaced as soon as they have expired. If you use solutions which are past their expiration date, the results will not be reliable.

Precautions

- Roche recommends to use the Activator for Cedex Bio HT systems as ISE Activator.
- Use only the Activator Bottle set for Cedex Bio HT systems which contains the appropriate 11 mL plastic bottles.
- Make sure you read all the warning labels on the cassettes.
- Use protective gloves to avoid direct contact with sample material.
- Remove any spillage of sample material immediately.

► To replace ISE Solutions on the ISE rack

1. Open the rack access panel on the front of the instrument.
2. Remove the ISE rack.
3. Open the rack cover.
4. Replace the solutions, as required.
5. Close the rack cover.
6. Reinstall the ISE rack.
7. You are prompted to indicate the solution(s) you have replaced. Click the corresponding button(s).

Position of ISE solutions on the rack

The default positions are as follows:

Rack position	Solution
1	Diluent (for example SDR2)
2	Activator Remove the cap from this bottle before placing it on the ISE rack.
3	ISE Etcher Do not use this solution after its expiration date.
4	ISE Solution 3 (Sol-3) Do not use this solution after its expiration date.
5	ISE Solution 2 (Sol-2) Do not use this solution after its expiration date.
6	ISE Solution 1 (Sol-1) Do not use this solution after its expiration date.
7	Diluent (for example, NaCl)
8	ISE Deproteinizer Do not use this solution after its expiration date.

Warning

- *You must not use any solution or reagent that is past its expiration date. The use of expired solutions will yield wrong results.*
- *Bottles on the ISE rack must be capped. This does not apply to the Activator.*
- *Confirm replacement only for bottles that have been exchanged. Otherwise, the monitoring of the bottle volume will be incorrect*
- *Confirm replacement for bottles that have been interchanged on the ISE rack. Prior to this, you have to change the rack positions for the ISE solutions and/or diluents. Use Configuration / Lab / Reserve Positions.*

Tips

- The positions of solutions on the ISE rack are user defined. To check the actual positions, as defined for your system, use the ISE tab in the Status work area.
- You can change the rack positions for the ISE Solutions. Use Configuration / Lab / Reserve Positions.
- When you click the button to indicate the ISE Solutions that you have replaced, the counters are reset to zero.
- The amount of remaining ISE Etcher and ISE Deproteinizer is calculated from the number of pipette actions that have been performed.
- The remaining amount of Activator and ISE Solution 1, 2, and 3 is determined by level detection.
- After replacement and confirmation of the ISE solution and/or diluent bottle on the ISE rack, the appropriate bottle volume is assigned to the defined ISE rack position for the correct volume management.

Replace bottles on ISE module

Overview

This is a general procedure, not a service action.

The ISE tab in the Status work area gives information about the status of the solutions on the ISE module. They must be replaced before the bottle is empty.

The ISE module must be in Standby, but the instrument can be running non-ISE tests.

Warning

You must perform the service action Prime ISE calibrators after replacing solutions on the ISE module. This ensures that no traces of the previous calibrator remain in the tubing and therefore prevents drift in the results.

Tools and materials

- ISE Calibrator Direct Bio HT
- ISE Calibrator Indirect Bio HT
- ISE Reference Electrolyte Bio HT
- Protective gloves

Hazards

- The ISE module, including the tower, fluid waste, tubing, and electrodes, is potentially infectious.
- Sample material is potentially infectious.
- There is a danger of cauterization and poisoning through skin contact with the reagents.

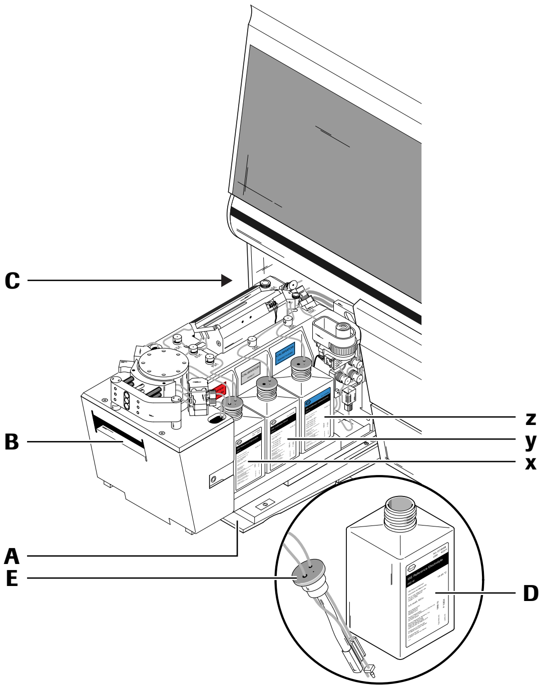
Precautions

- Make sure you read all the warning labels on the cassettes.
- Use protective gloves to avoid direct contact with sample material.
- Remove any spillage of sample material immediately.

► **To replace ISE Calibrators/Reference electrolyte on the ISE module**

1 Wait until the system is in Standby.

2 Open the ISE access panel (A).



3 Pull out the ISE module using the handle (B).

Pull the module out until the spring catch (C - attached to the rear of the module) is engaged.

4 Open a new bottle.

5 Remove the empty bottle (D) from the ISE module.

6 Remove the floater (E) from the empty bottle.

7 Insert the floater into the new bottle.

8 Place the new bottle in the assigned position on the ISE module.

9 Repeat steps 4 through 8 for all empty bottles.

10 Release the spring catch and slide the ISE module back until it clicks into place.

11 Perform the service action Prime ISE calibrators.

Tip

Place the solutions in their correct positions (x, y, or z) on the ISE module. The positions are color-coded to match the color on the corresponding bottle label:

Solution	Color of position and bottle label	See above
ISE Reference Electrolyte	Red	x
ISE Calibrator Direct	Gray	y
ISE Calibrator Indirect	Blue	z

Replace ISE tower

Overview *This is a general procedure, not a service action.*

The ISE module cannot operate if the ISE tower is blocked. Flags or messages will be generated if you need to clean or replace the ISE tower.

You can replace the ISE tower if cleaning it manually does not have the required effect.

► **To replace the ISE tower**

1. Perform the service action Clean ISE tower manually.
2. Exchange the existing ISE tower with a replacement at the appropriate step.

ISE Performance Check

Overview	*This is a general procedure, not a service action.* This procedure needs to be performed on request for ISE troubleshooting. It checks the performance of each electrode by measuring 10 times ISE Calibrator Direct and ISE Calibrator Indirect respectively.
Duration	10 minutes
Interval	None
Begin of Day	No
System state	Standby
Tools and materials	• ISE Calibrator Direct Bio HT • ISE Calibrator Indirect Bio HT • ISE Reference Electrolyte Bio HT
Hazards and precautions	See “General safety precautions” on page F-16.

► **To check the ISE performance**

1. Select ISE Performance Check in the Service work area.
2. Click Perform.

   The Service Actions dialog box is displayed; follow the online prompts as required.
3. ISE Calibrator Direct is transported to the electrode block and remains there for 45 seconds [automatic step].
4. Subsequently ISE Calibrator Direct is transported again to the electrode block and the first measuring starts [automatic step].
5. Step 4 is repeated ten times.
6. ISE Calibrator Indirect is transported to the electrode block and remains there for 45 seconds [automatic step].
7. Subsequently ISE Calibrator Indirect is transported again to the electrode block and the first measuring starts [automatic step].
8. Step 7 is repeated ten times.
9. Click Next.
10. Click Show Values.
11. The measured values, Mean, Min, Max, the Standard Deviation (SD) and the Coefficient of Variation (CV) for all electrodes in the respective modes are displayed.
12. Click Print.
13. Click Cancel.

Send the printout of the measured values to Roche Service.

ISE flags and troubleshooting

Solving problems with the ISE module

This chapter describes some of the common problems that you may get with the ISE module and the actions you should take to overcome them. It describes the result flags that may be generated with ISE measurements and also provides guidance for general troubleshooting procedures.

To avoid problems, always follow the service schedules defined for your system.

If you have any problems that you cannot resolve, contact Roche Service.

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About ISE flags

This section describes all the ISE flags generated by the *Cedex Bio HT* analyzer, their associated error messages, and the corresponding user actions.

ISE flags, like other flags, are automatically generated with results when the system detects a problem or a potential problem. When a flag is generated, it is displayed together with the result in the Results work area. When you print a result, the flag is also printed.

Flags and error messages

Some ISE flags trigger error messages if they appear in a consecutive sequence. A flag counter monitors the number of consecutive flags and triggers an error message if the counter limit is reached. Each flag has its own counter and counter limit as listed in “Flags and user actions” on page F-41.

If a single ISE measurement does not generate a particular flag, the flag counter is reset to zero.

With a single flag, repeat the measurement or the calibration. An error message indicates a more persistent error requiring further action, for example, performing service actions.

Flag priority

If the conditions in the ISE module are such that multiple flags could be generated for a single ISE measurement, only the flag with the highest priority is displayed (or printed) with the result. The lower the number, the higher the priority. The priority of each flag is given in the flag description. All other flags with lower priority are shown in the result details.

Results without flags are automatically within the reference range and can be considered to be error-free.

Flags and result handling

When a flag occurs, processing is dependent upon result handling, which is defined in Configuration / Result Handling / Results. You can check the details held in result handling to review what your system does when it generates specific flags.

The system action can be different for calibrations, controls, and samples.

Flags and user actions

{The action you need to take in response to a flag for an ISE measurement depends on whether:

- Only a single flag was generated.
- The flag was repeated and the error message for that flag was displayed.

Both cases are described in the flag descriptions.

Where a flag description gives a list of recommended actions, work through each step in turn until you have solved the problem. Proceed to the next step only after you have completed the previous one.

List of flags

The following table lists the flags in alphabetical order:

Flag	Priority	Counter limit	Message ID	See page
AIR FLUID	11	5	14.3248.08.023.xxx	F-43
AIR ISECAL	12	5	14.3248.08.017.xxx	F-43
ISE UNSTAB	13	5	14.3248.08.031.xxx through 14.3248.08.038.xxx 14.3248.08.018.xxx (leakage)	F-44
NO FLUID	7	3	14.3248.08.010.xxx 14.3248.08.011.xxx 14.3248.08.047.013 14.3248.08.048.013	F-45
NO ISECAL	8	3	14.3248.08.027.xxx	F-45
OUT OF RNG	26	None	None	F-46
SEG FLUID	9	3	14.3248.08.012.xxx	F-46
SEG ISECAL	10	3	14.3248.08.028.xxx	F-47
SOL 1 F DEV	28	None	None	F-47
< TEST RNG	30	None	None	F-48
>TEST RNG	31	None	None	F-48

The following flags do not generate messages:
OUT OF RNG, SOL 1F DEV, <TEST RNG, and >TEST RNG.

Messages number format

When a repeated flag generates a message, the message number has the format: aa.bbbb.cc.ddd.xxx as shown in the table above. You can uniquely identify a message by the second (cc) and the third (ddd) groups of digits.

For example, in the message 14.3248.08.012.xxx, the digits 08.012 identify the message; xxx means “don’t care”, that is, these digits are not significant.

If a message box is displayed, you can get detailed information by clicking Help.

"Message Help" on page A-68

Terminology The following terminology is used in the flag descriptions that follow:

FLUID

Any liquid (sample, control, calibrator, or other solution) that is introduced into the ISE tower.

ISECAL

ISE Calibrator Direct or ISE Calibrator Indirect.

SEG

A segment of fluid that is drawn past the fluid sensor and, therefore, past the electrodes. Fluid segments are separated by air segments.

Flags and service actions Some user actions for flags include performing service actions.

Chapter 14, "Service actions" and Chapter 18, "ISE service actions"

Flag descriptions

AIR FLUID

Meaning The length of the fluid segment was too short.

Message ID 14.3248.0814.3248.08.023.xxx

Possible cause The sample segment was too short because:

- Air bubbles are present.
- The ISE tower is clogged.
- The dosing from the sample probe is inaccurate.
- The ISE module tubing is leaking or blocked, or it is not conditioned.
- Mixing is too vigorous (for the indirect mode).

Recommended actions If only one result is flagged:

1. Repeat the measurement.
2. Check the sample tubes and ISE solution bottles for foaming.

If the error message is displayed:

1. Perform the service action Activate electrodes.
2. Replace the ISE tower (use the service action Clean ISE tower manually).
3. Perform the service action Deproteinize probes.
4. Check the ISE module tubing for leaks or blockages.
5. Replace the ISE module tubing (Use the service action Replace ISE module tubing).
6. Contact Roche Service.

AIR ISECAL

Meaning The length of the calibrator segment was too short.

Message ID 14.3248.08.030.xxx

Possible cause The calibrator segment was too short because:

- Air bubbles are present.
- The ISE distribution block is leaking or blocked.
- The ISE module tubing is leaking or blocked.

Recommended actions If only one result is flagged:

1. Repeat the measurement.
2. Ensure that the ISE Calibrators on the ISE module are available and check the level of liquid; replace if necessary.
3. Check the ISE module tubing and the ISE distribution block for leaks or blockages.

If the error message is displayed:

1. Perform the service action Prime ISE calibrators.
2. Check the ISE module tubing and the ISE distribution block for leaks or blockages.
3. Contact Roche Service.

ISE UNSTAB

Meaning, cause, and action depend on the message ID, which are divided into two groups:

- 14.3248.08.031.xxx through 14.3248.08.038.xxx
- 14.3248.08.018.xxx (leakage)

Meaning The signal from the electrode(s) was not stable during the measurement.

Message IDs 14.3248.08.031.xxx through 14.3248.08.038.xxx

Possible cause The ISE measurements (mV Values) are unstable because:

- There are air bubbles in the measuring segment.
- The concentration of electrolyte in the sample is too low (for example, dialyzed samples).
- The pH of the sample is too low (for example, pH < 5.5).
- One or more O-rings are missing or damaged.
- The electrodes have not been serviced.
- The expiration date of the electrode has passed or the electrode is damaged.
- The ISE Reference Electrolyte tubing is blocked or leaking.
- The floater of the ISE Reference Electrolyte bottle is blocked.
- The preamplifier is not working properly.

Recommended actions If only one result is flagged:

1. Repeat the measurement.
2. Repeat the measurement with a suitable sample (where pH > 5.5 and correct electrolyte concentration) to establish that the ISE module is OK.
3. Check the position and condition of the O-rings and replace if necessary.

If the error message is displayed:

1. Perform the service action Activate electrodes.
2. Perform the service action Electrode service.
3. Replace expired electrodes and perform the service action Electrode service.
4. Check the ISE Reference Electrolyte tubing for leaks or blockages.
5. Check the floater of the ISE Reference Electrolyte bottle for blockages.
6. Contact Roche Service.

Meaning A fluid leakage in the electrode block was detected

Message ID 14.3248.08.018.xxx (leakage)

Possible cause The ISE measurements (mV Values) are unstable because:

- One or more O-rings are missing or damaged.
- The electrodes and/or the electrode block are not dry.

Recommended actions

1. Press F12 (Stop).
2. In the Stopping dialog box, select Stop when in-progress test have completed, then click OK.
3. Remove electrodes and clean and dry the electrode block.
4. Dry electrodes.
5. Check the position and condition of the O-rings and replace if necessary.

6. Re-install the electrodes.
7. Contact Roche Service if the message reappears.

NO FLUID

Meaning

No fluid was detected at one of the fluid sensors (1 or 2).

Message IDs

14.3248.08.010.xxx

14.3248.08.011.xxx

Possible cause

The fluid sensors could not detect any liquid because:

- The liquid was not pipetted.
- The ISE tower is clogged.
- The ISE module tubing is blocked.
- Fluid sensor 1 or 2 is defective.

Recommended actions

If only one result is flagged:

1. Repeat the measurement.
2. Check the sample tubes for clots.
3. Ensure ISE solution bottles on the ISE rack are available and check the level of liquid; replace if necessary.

If the error message is displayed:

1. Replace ISE tower (use the service action Clean ISE tower manually).
2. Check ISE module tubing for leaks or blockages.
3. Contact Roche Service.

NO ISECAL

Meaning

No calibrator was detected at fluid sensor 2.

Message ID

14.3248.08.027.xxx

Possible cause

Fluid sensor 2 could not detect a calibrator because:

- One or more calibrator bottles are not available.
- The ISE module tubing is leaking or blocked.
- The ISE distribution block is leaking or blocked.
- Fluid sensor 2 is defective.

Recommended actions

If only one result is flagged:

1. Repeat the measurement.
2. Ensure that the ISE Calibrators on the ISE module are available and check the level of liquid; replace if necessary.

If the error message is displayed:

1. Perform the service action Prime ISE calibrators.
2. Check the ISE module tubing and the ISE distribution block for leaks or blockages.
3. Contact Roche Service.

OUT OF RNG (ISE)

Meaning The electrode slopes were out of range.

Message ID None

Possible cause Electrode slope out of range. This flag appears with calibrations because:

- There are problems with the ISE solutions on the ISE rack.
- There are problems with the electrodes or an improperly serviced ISE module.
- The ISE Reference Electrolyte tubing is blocked or leaking.
- The floater of the ISE Reference Electrolyte bottle is blocked.
- The dosing from the sample probe is not accurate.
- The preamplifier is not working properly.

Recommended actions If only one calibration is flagged:

1. Repeat the calibration.
2. Repeat the calibration with fresh ISE solutions 1, 2, and 3, and check visually the correct flow of all ISE solutions and the ISE Reference Electrolyte.

If successive calibrations are flagged:

1. Repeat the calibration with fresh ISE solutions 1, 2, and 3, and check visually the correct flow of all ISE solutions and the ISE Reference Electrolyte.
2. Check whether the electrode expiration date has passed. Replace the electrodes, if necessary.
3. Perform the service action Electrode service.
4. Perform the service action Deproteinize probes.
5. Check ISE Reference Electrolyte tubing for leaks or blockages.
6. Check the floater of the ISE Reference Electrolyte bottle for leaks or blockages.
7. If the slopes of all electrodes are zero, replace the reference electrode.
8. Contact Roche Service.

SEG FLUID

Meaning The end of the fluid segment was not detected.

Message ID 14.3248.08.012.xxx

Possible cause The end of the sample segment was not detected. It takes too long for a sample segment to reach the electrodes because:

- The ISE tower is clogged.
- The ISE module tubing is leaking or blocked.

Recommended actions If only one result is flagged:

1. Repeat the measurement.

If the error message is displayed:

1. Perform the service action Activate electrodes.
2. Replace the ISE tower (use the service action Clean ISE tower manually).
3. Check the ISE module tubing for leaks or blockages.
4. Replace the ISE module tubing, if necessary (Use the service action Replace ISE

module tubing).

5 Contact Roche Service.

SEG ISECAL

Meaning The end of the calibrator segment was not detected.

Message ID 14.3248.08.028.xxx

Possible cause The end of the calibrator segment was not detected. It takes too long for a calibrator segment to reach the electrodes because:

- The ISE module tubing is leaking or blocked.
- The ISE distribution block is leaking or blocked.

Recommended actions If only one result is flagged:

1. Repeat the measurement.
2. Ensure that the ISE Calibrators on the ISE module are available and check the level of liquid; replace if necessary.

If the error message is displayed:

1. Perform the service action Prime ISE calibrators.
2. Check ISE module tubing and ISE distribution block for leaks or blockages.
3. Contact Roche Service.

SOL 1 F DEV

Meaning Solution 1 factor is not within the permissible range.

Message ID None

Possible cause Deviation of Sol 1 Factor. This flag occurs with calibrations because:

- The dosing from the sample probe is not accurate.
- The ISE tower is blocked.
- There may be problems with the ISE module tubing, the electrodes, or an improperly serviced ISE module.
- Contaminated calibrator or bottle placed in wrong position.

Recommended actions If only one calibration is flagged:

1. Repeat the calibration.

If successive calibrations are flagged:

1. Check whether the calibrators are in the correct positions.
2. Perform the service action Activate electrodes.
3. Replace the ISE tower (use the service action Clean ISE tower manually).
4. Perform the service action Prime ISE calibrators.
5. Check whether the electrode expiration date has passed. Replace the expired electrode, if necessary, and perform the service action Electrode service.
6. Check the ISE module tubing for leaks or blockages.
7. Contact Roche Service.

<TEST RNG

Meaning	The measured value is below the test range.
Message ID	None
Possible cause	The actual concentration in the sample is below the test range
Recommended action	• Check the ISE reading (mV).

>TEST RNG

Meaning	The measured value is above the test range.
Message ID	None
Possible cause	The actual concentration in the sample exceeds the test range.
Recommended action	• Check the ISE reading (mV).

General ISE troubleshooting

This section identifies some common problems that do not necessarily generate flags or messages.

Poor accuracy

Results are reproducible but do not match the known values.

► ISE tower clogged or dirty

1. If the ISE tower is clogged, replace it.
2. If the ISE tower is dirty, perform the service action Clean ISE tower automatically or Clean ISE tower manually.
3. If this does not fix the problem, perform the service action Replace ISE tower.

You may have to perform the service action Clean ISE tower automatically more frequently. If so, reduce the service interval in the Service work area.

► ISE solutions, calibrators, or electrodes expired

1. Check the expiration date of all ISE solutions, calibrators, and electrodes.

► Probes clogged or dirty

1. Perform the service action Deproteinize probes.
2. Perform the service action. Replace probe C, if necessary.

► Begin of Day actions not properly performed

1. Perform the service action Electrode service.
2. Perform the service action Deproteinize probes.

► Mixing, washing, or drying in the ISE tower not completed properly

1. Perform the service action Clean ISE tower automatically or Clean ISE tower manually.
2. Contact Roche Service.

► ISE Reference Electrolyte not present or flow not sufficient

1. Check whether there is enough ISE Reference Electrolyte in the bottle.
2. Check the ISE Reference Electrolyte flow through the reference electrode.

   The ISE Reference Electrolyte flow should look like a bead chain. If it does not, check the ISE Reference Electrolyte tubing and the floater, for blockage (salt deposits) or leaks.
3. Remove any blockages and replace the tubing, if necessary.
4. Replace the ISE module tubing, then perform the service actions: Condition ISE module tubing and Prime ISE calibrators.

Results not reproducible

Results are obtained, but different measurements give different results.

► ISE tower clogged or dirty

1 If the ISE tower is clogged, replace it.
2 If the ISE tower is dirty, perform the service action Clean ISE tower automatically or Clean ISE tower manually.
3 If this does not fix the problem, perform the service action Replace ISE tower.

You may have to perform the service action Clean ISE tower automatically more frequently. If so, reduce the service interval in the Service work area.

► All electrodes:

1 Perform the service action Electrode service.
2 Calibrate and rerun the tests.

► Clogged or dirty sample probes

1 Perform the service action Deproteinize probes.
2 Replace probes, if necessary.

► Mixing, washing, or drying in the ISE tower not completed properly

1 Perform the service action Clean ISE tower automatically or Clean ISE tower manually.
2 Contact Roche Service.

► Electrode slope out of range for sodium or potassium

1 Repeat the calibration, with fresh ISE solutions 1, 2, and 3.
2 Perform the service action Electrodes service.
3 Repeat the calibration.
4 Replace the ISE tower (use the service action Clean ISE tower manually).
5 Check the expiration date of the electrodes. Perform the service action Replace electrode, if necessary.

All slopes out of range

The measured slopes are outside acceptable limits.

► ISE solutions expired

Check the expiration date of all ISE solutions and replace those which have expired.

► ISE tower clogged or dirty

1 If the ISE tower is clogged, replace it.
2 If the ISE tower is dirty, perform the service action Clean ISE tower automatically or Clean ISE tower manually.

3 If this does not fix the problem, perform the service action Replace ISE tower.

You may have to perform the service action Clean ISE tower automatically more frequently. If so, reduce the service interval in the Service work area.

► Probes clogged or dirty

1. Perform the service action Deproteinize probes.
2. Perform the service action Replace probe C, if necessary.

► ISE Reference Electrolyte or reference electrode expired

Check the expiration and replacement dates of the ISE Reference Electrolyte and the reference electrode, and replace if necessary.

► ISE Reference Electrolyte not present or flow not sufficient

1. Check whether there is enough ISE Reference Electrolyte in the bottle.
2. Check the ISE Reference Electrolyte flow through the reference electrode.

   The ISE Reference Electrolyte flow should look like a bead chain. If it does not, check the ISE Reference Electrolyte tubing and the floater, for blockage (salt deposits) or leaks.
3. Remove any blockages and replace the tubing, if necessary.
4. Replace the ISE module tubing, then perform the service actions Condition ISE module tubing and Prime ISE calibrators.

► ISE module not used for one or more days

Perform the service action Activate electrodes several times.

Configuration G

Part G describes the Configuration work area and gives step-by-step procedures for some common configuration tasks. You must have the required user access level to perform these tasks.

Configuration

Modifying your system configuration

This chapter provides an overview of common configuration procedures for the *Cedex Bio HT* analyzer.

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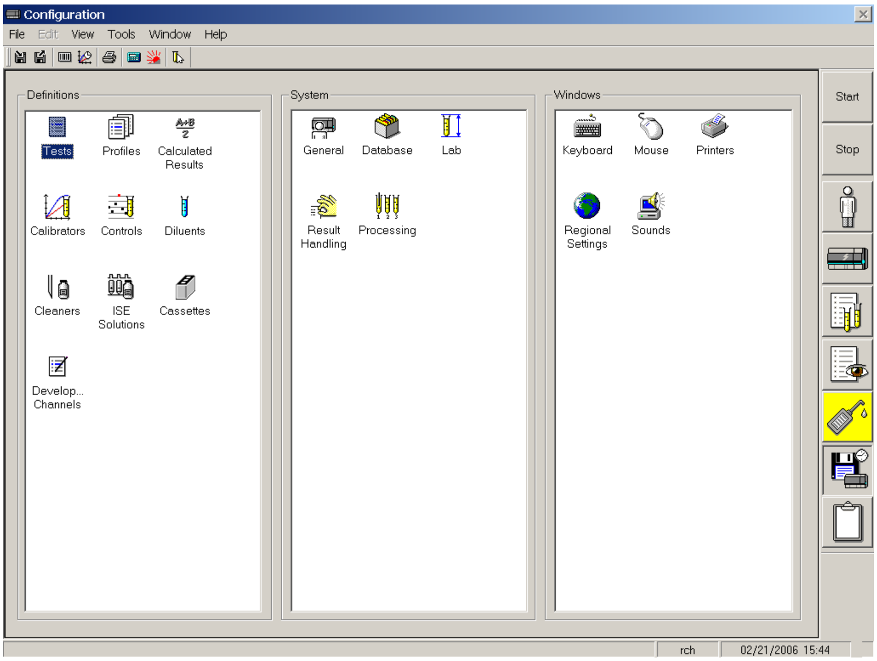
Configuration overview

Configuration allows you to access the database and make modifications to support a wide range of system functionality requirements. The procedures included here explain how, for example, you can modify test definitions, profile, calculated result, calibrator, and control details.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ISE Solutions
Cassettes
Develop... Channels
System
General
Database
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Processing
Windows
Keyboard
Mouse
Printers
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Sounds
Start
Stop
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Definition tasks

The tasks included are designed to help you become familiar with the following definitions:

- Tests
- Profiles
- Calculated results
- Calibrators
- Controls
- Diluents
- Cleaners
- ISE Solutions
- Cassettes
- Development Channels (optional)

Configuration comprises three groups: Definitions, System, and Windows. However, only those tasks primarily associated with the Definitions group have been included in this manual. The exception is that the System group tasks of defining user access and level have also been included.

The primary function of each of the three groups in the Configuration work area is summarized in the table below.

Use this group	To review or modify
Definitions	Definitions of tests, calibrators, controls, profiles, calculated results, cassettes, cleaners, ISE solutions, diluents, archives, and Development Channels (optional).
System	System settings, including general, database, lab setup, result handling, and processing.
Windows	Windows settings, including printer, keyboard, mouse, regional and sound settings.

Further tasks

- Archiving and reloading definitions
- User Access

You find more information about the Configuration work area in the online Help.

About the Definitions group

Generally, definitions are loaded during the installation process where default values are set by Roche Service personnel. You can subsequently create new definitions or modify existing ones using the dialogs in the Configuration Definitions group. You can do so only if you have the appropriate user access level.

Definitions group functions are as follows:

Tests

A test definition contains all the information the system needs in order to run a test including the names of the calibrators, controls, cleaners, and diluents.

Click the Tests icon to review, load, modify, or delete test definitions.

Test Group, Sequence, and Class

You can define groups of tests for use in Orders and the sequence of the test buttons displayed. You can also define test classes for result handling purposes.

From the Test Definitions dialog box, click the Class/Group button to define and modify test groups, sequence and classes

Profiles

A test profile is a named group of tests. In orders, tests are added to an order by clicking a button (which may have the profile name on it) which adds all the tests in the profile to the order.

Click the Profiles icon to review, create, modify, or delete test profile definitions.

Calculated results

A calculated result is the arithmetical combination of two or more test results to produce a new value. A calculated result definition contains information about the formula and the tests to be used in the calculation.

Click the Calculated Results icon to review, create, modify, or delete a calculated result definition.

Calibrators

A calibrator definition contains a list of all tests that are to be calibrated using a specific calibrator. It also contains details for individual calibration points.

Click the Calibrators icon to review, create, modify, load, or delete a calibration definition.

Controls

A control definition contains a list of all the tests for which the control is to be used and, for each test, what type of control (precision, accuracy, or limit) it is.

Click the Controls icon to review, create, modify, load, or delete a control definition.

Diluents

A diluent definition provides information about a diluent and the tests for which it is used.

Click the Diluents icon to review, load, or delete a diluent definition.

Cleaners

A cleaner definition provides information about a cleaner and the tests with which it is used.

Click the Cleaners icon to review or delete a cleaner definition.

ISE solutions

ISE solutions are solutions used to perform calibrating, deproteinizing, etching, and activating operations on the ISE module.

Click the ISE Solutions icon to review, load or delete the existing definitions.

Cassettes

A cassette definition provides information about a cassette including the test(s) for which the cassette is used, and a list of cassette and lot numbers that have been used for this type of cassette.

Click the Cassettes icon to review, load, or delete a cassette definition.

Development Channels

Development Channels are used to run non-Roche reagents on *Cedex Bio HT* systems. Up to 10 Development Channels can be implemented. This function is optional and has to be activated with an extra license.

Call Roche Service for further information.

About test definitions

You use the Configuration Test Definitions dialog box to load, review and modify test definitions. The dialog box lists all the currently installed tests on the left. When you select a test, the details are automatically listed on the right.

What is a test definition?

A test definition contains all the information the system needs to run tests, including:

- Basic test information, such as names and number
- The default sample type
- Calibrator name and calibration intervals
- Automatic post-dilution/post-concentration factors
- Controls and control intervals
- Correlation factors and laboratory units
- Result evaluation and reference ranges

► To use the Configuration Test Definitions dialog box:

1 Click Configuration on the navigation bar.

2 Double-click the Tests icon in the Definitions group.

Loading and modifying test definitions

When loading test definitions, all required files are loaded. You are informed before existing files are overwritten.

► To install and load test definitions

1 In the Definition group, double-click Tests.

2 Click Load... to open the Load dialog box.

3 Specify the path where the source files are located.

4 Click OK.

5 Select the tests to be installed.

The Load Complete Test Definitions dialog box is displayed.

6 Select the Keep Old Lab Settings check box to ensure that user defined parameters are preserved. (This box is selected by default.)

7 Click Load.

8 The Load definitions in progress window is displayed. Do not click Stop.

9 Click Cancel to return to the ID tab. The newly installed tests are listed in the installed tests panel.

Tips

- The instrument must be in Standby or Sleeping state.

- User defined test parameters comprise the definitions made on the Configuration Test Definitions dialog box (Configuration / Test).

► To view and modify basic test definitions

1 Click the ID tab.

2 Select a test from the Installed Tests list. Basic test details are displayed on the right.

3 Modify the Short Name, Long Name and Test No if required.

4 Click Save.

Tips

- The instrument must be in Standby or Sleeping state.
- Short Name is maximum eight alphanumeric characters.
- Long Name is maximum 30 alphanumeric characters.
- Test No is a number in the range of 1 through 999.
- The Short Name, Long Name, and Test Number are mandatory and must be unique for tests, profiles, and calculated results.
- The ID is assigned by Roche and cannot be changed.

► To modify default sample type and calibration details

1 Click the General tab.

2 Select the required test from the Installed Tests list.

3 Modify the Default Sample Type by selecting an alternative from the list.

Use Configuration / Lab / Sample Types to define the list.

4 Modify the Calibration details:

a. Select one of the Replicate options. (No replicates for ISE.)

b. For the Main Interval, select the type of calibration interval and type the number of days required for the interval.

5 Click Save.

Tip

The calibrator required for each test is automatically added when the test is entered. Modifications are only necessary where another calibrator is used.

► To modify dilutions and/or concentrations

1 Click the Dilutions tab.

2 Select the required test from the Installed Tests list.

3 Select Automatic Dilutions (Off) if no automatic dilutions are required. Automatic Dilutions (sequential) should be selected to allow post actions as and when required.

4 Select the dilution and type the dilution or concentration factor required for the test.

5 Click Save.

Tip

The default post-handling factors are specific to each test and should not be modified.

► To modify control parameters and the interval sequence

1. Click the Control tab.
2. Select the required test from the Installed Tests list.
3. Select the QC Treatment check box to ensure that each control is checked according to Precision, Accuracy, and Limit rules.
4. Select the Interval check box to perform controls automatically.
5. Select Tests and type the number of tests that constitute one interval, or select Hours and type the number of hours that constitute one interval.
6. For each control you have selected, you can select the After Cal check box if you want the control to be run automatically after every calibration.
7. You can also select an interval sequence (one through six) for each control. If more than one control is defined, select consecutive Interval Sequence numbers.
8. Click Save.

Tips

- Controls, unlike calibrators, are not automatically installed with each test and should be selected as required.
- Control intervals can be based upon the number of tests run, time (number of hours), or after calibration.
- For details on controls, see Chapter 20, “Quality controls”.

► To modify correlation and default unit parameters

1. Click the Laboratory tab.
2. Select the required test from the Installed Tests list.
3. Modify the Correlation Factor and Offset as required.
4. Change the Lab Unit from the default if required. Modify the Lab Unit Factor.
5. Select the number of Decimal places to be displayed in the reported result.
6. Click Save.

► To modify reference and critical ranges

1. Click the Evaluation tab.
2. Select a test from the Installed Tests list.
3. In the Result Evaluation Mode box, select None, Reference, or Cutoff.
4. Modify the appropriate reference or critical ranges, or the cutoff limit as required.
5. Click Save.

► To delete a test definition

1. From any tab, select one or more tests from the installed test list and click Delete.
2. Click Yes to confirm the deletion in the Confirm Delete dialog box.

Preconditions

- Remove the associated calibrator and control racks.
- Make sure there are no orders pending for this test.
- Make sure all results associated with this test are accepted.

Tips

- If you decide not to delete a selected test after pressing the Delete key, you can click No or Cancel in the Confirm Delete dialog box.
- If results exist for the selected test definition, another Confirm Delete dialog box appears to allow you to confirm the deletion of results associated with the test.

Creating and modifying test groups, sequences, and classes

Test groups are used in Orders to reduce the number of test buttons displayed. Test sequences arrange the way test buttons are displayed in Orders, and Test classes are used in Result handling.

Profiles are not affected by these definitions.

You may not have the necessary user access level to create and modify test groups, sequences, and classes. Ask your system manager for assistance.

To define and modify test groups, sequence and classes, click the Class/Group button from the Configuration Test Definitions dialog box.

► To create a new test group

1. Click Class/Group.
2. Click the Test Groups tab
3. Click New.
4. Type a Group Name for the new group.
5. Select tests to be included in the new group from the Installed Tests list. Click Add to add them to the Tests in Group list.
6. Click Save.

Tips

- Group Name is up to nine alphanumeric characters and must be unique.
- Use Remove to remove a test from the Test in Group list and return it to the Installed Tests list.

► To modify a test group

1. Click Class/Group.
2. Click the Test Groups tab
3. Select a Group Name from the Test Groups list.
4. Use Add to move installed tests to the Tests in Group list.
5. Use Remove to move Tests in Group tests to the Installed Tests list.

► To modify a test sequence

1. Click Class/Group.
2. Click the Test Sequences tab.
3. Select the Sequence in which test buttons in Orders are to be displayed.
4. Click Save.

Tips

- Sequence can be arranged in alphabetical order by Test Class, or you can select your own sequence (Custom).
- The Move buttons are active only if you select Custom.
- Test Sequence defines the display of the test buttons on the Sample tab of the Order work area.

► To create a new test class

1. Click Class/Group.
2. Click the Test Classes tab.
3. Click New.
4. Type a Class Name for the new test class.
5. Select tests to be included in the new class from the Available Tests list. Click Add to add them to the Tests in Class list.
6. Click Save.

Tips

- Each test appears in one test class only.
- Roche defined test classes are displayed in blue, user defined test classes are displayed in black.
- Class Name is up to nine alphanumeric characters.
- The Available Tests list shows all tests that are not yet assigned to a class.
- Use Remove to remove a test from the Tests in Class list and return it to the Available Tests list.
- Test classes are used for result handling.

► To modify a test class

1. Click Class/Group.
2. Click the Test Classes tab.
3. Select a Class Name from the Test Classes list.
4. Use Add to move available tests to the Tests in Class list.
5. Use Remove move Tests in Class to the Available Tests list.
6. Click Save.

Tip

Roche defined test classes are displayed in blue, user defined test classes are displayed in black.

About profile definitions

You use the Configuration Profile Definitions dialog box to create new profile definitions, or modify or delete existing ones.

What is a profile? You use profiles in the Orders work area to request groups of tests quickly, without having to select individual tests.

► To use the Configuration Profile Definitions dialog box:

1. Click Configuration on the navigation bar.
2. Double-click the Profiles icon in the Definitions group.

Creating and modifying profile definitions

► To create a new profile definition

1. Click the ID tab.
2. Click New.
3. Type the profile name. It can have up to eight alphanumeric characters.
4. Type a profile number in the range of 910-930. This number must be unique among the test, profile and calculated results (ratio) numbers.
5. Click the Tests tab and click one or more test buttons to select the tests for the profile.
6. Click Save.
7. Click Close.

► To load a Roche profile

1. Click Load.
2. Specify the path where the source files are located. The default path is “C:/Roche/Instrument/TAS”.
3. Select the profile to be installed.
4. Perform the following steps for each profile:
   - Click the ID tab.
   - Modify the short name of the profile, if required. The short name can have up to eight alphanumeric characters.
   - Modify the long name of the profile, if required. The long name can have up to 30 alphanumeric characters.

► To view and modify profile definitions

1. Click the ID tab.
2. Choose a Profile from the list.
3. Modify the Profile Name or Profile No as required.
4. Click the Tests tab to modify the tests to be included in this profile.
5. Click one or more test buttons to select tests for the profile.
6. Click Save.

► To delete a profile definition

1. From any tab, select one or more Profiles from the list.
2. Press the Delete key or click Delete.
3. Click Yes in the Confirm Delete dialog box.

Tip

If you decide not to delete a selected profile after pressing the Delete key, you can click No or Cancel in the Confirm Delete dialog box.

About Calculated Result definitions

You use the Configuration Calculated Result Definitions dialog box to add calculated result definitions, or modify or delete existing definitions.

What is a calculated result?

A calculated result is a mathematical relationship involving one or more test results and, optionally, numerical constants. The system automatically calculates a calculated result if all the tests specified in the calculated result definitions are requested in an order. Calculated results use the results from 1 to 4 tests in a mathematical formula to obtain another value, which can then be checked against a reference range and flagged.

► To use the Configuration Calculated Result Definitions dialog box:

1. Click Configuration on the navigation bar.
2. Double-click the Calculated Results icon in the Definitions group.

Creating and modifying calculated result definitions

You can create and modify calculated result definitions using the different tabs in the dialog box.

► To create a calculated result definition

1. Click the ID tab.
2. Click New.
3. Type in the Short Name, Long Name, and the Calc. Result No. These definitions are mandatory.
4. Select the Common Cuvette box.

   This is necessary to make sure that the calculated result is correct. For example, when using predilution, it is necessary that all tests required for a calculated result are prediluted from the same cuvette. The Common Cuvette feature is currently required for HbA1cWB only. The Common Cuvette box is selected by default.
5. Define formula, calculated result unit, and reference ranges for the new calculated result definition as required.
6. Click Save.

Tips

- Short Name consists of up to eight alphanumeric characters.
- Long Name consists of up to 30 alphanumeric characters.
- The calculated result number is in the range of 1 through 999, and is unique for tests, profiles, and calculated results.
- Calculated result numbers 910-930 are for customer defined calculated results.
- When creating formulas, up to four tests (A - D) and up to four factors (w - z) can be defined.
- You can use the standard mathematical operations “+”, “-”, “*”, and “/”, as well as the brackets “(” and “)”. The syntax is checked by the system when you click Save.

- There are predefined Roche calculated results available for loading.

► To load a Roche calculated result

1. Click Load.
2. Specify the path where the source files are located. The default path is “C:/Roche/Instrument/TAS”.
3. Perform the following steps for each calculated result:
   - Click the ID tab.
   - Modify the short name of the calculated result, if required. The short name can have up to eight alphanumeric characters.

     Be aware that the short name affects the calculated result name in the user interface.
   - Modify the long name of the calculated result, if required. The long name can have up to 30 alphanumeric characters.
   - Click the Laboratory tab.
   - Enter the correlation factor and the correlation offset if correlating two different methods.
   - Enter the unit of the calculated result (ratio) and the factor and offset if the lab units are different from the specified units, if required.
   - Enter the number of decimal places of the result.
   - Click the Evaluation tab.
   - Enter a general range and critical range, if required.
   - Click Add and enter reference ranges.

► To view and modify calculated result definitions

1. Click the ID tab.
2. Choose a calculated result from the list.
3. Modify the Short Name, Long Name or Calc. Result No. as required.
4. Select or clear the Common Cuvette box.
5. To modify a formula, calculated result units, and / or reference ranges for the calculated result definition, click the Formula, Laboratory, or Evaluation tab and modify the values as required.
6. Click Save.

Tip

- Steps 3 and 4 are only possible for customer calculated results, not for Roche calculated results.

► To delete a calculated result definition

1. From any tab, choose a calculated result from the list.
2. Press the Delete key or click Delete.
3. Click Yes in the Confirm Delete dialog box.

Tip

If you decide not to delete a selected calculated result after pressing the Delete key, you can click No or Cancel in the Confirm delete dialog box.

About calibrator and control definitions

Calibrator definitions

Once tests have been loaded, the corresponding calibrators are automatically installed in the Calibrators list. The Configuration Calibrator Definitions dialog box is used to update lot numbers and values for existing calibrators or to create a user defined calibrator.

“Setting up calibrators” on page B-154
“To update a calibrator lot number using the barcode pen or handheld barcode scanner” on page B-155

Control definitions

You use the Configuration Control Definitions dialog box to load control definitions, create a user defined control, or update the lot number and values for an existing control definition and enter values.

“Setting up controls” on page B-181
“To update lot specific values using the barcode pen or handheld barcode scanner” on page B-185

About cassette definitions

You can use the Configuration Cassette dialog box to define warning levels for each cassette or view the cassette history.

► To use the Configuration Cassette Definitions dialog box

1. Click Configuration on the navigation bar.
2. Double-click the Cassettes icon in the Definitions group.

Viewing and modifying cassette definitions

► To modify the warning level

1. Click the ID tab.
2. Select a cassette from the list to display the information on the right.
3. Modify the warning level.
4. Click Save.

Tips

- You cannot change any of the cassette details, apart from the Warning Level.
- Warning Level is used to generate a “tests low” warning message in Status. The entry is the percentage of tests remaining in the cassette.

► To view the cassette history

1. Click the History tab.
2. Select a cassette from the list to display the information on the right.

Tip

The Cassette History gives a list of the cassettes known to the system.

About cleaner definitions

You can use the Configuration Cleaner dialog box to view existing definitions, the cleaner history, and to load a new cleaner definition.

► To use the Configuration Cleaner Definitions dialog box:

1 Click Configuration on the navigation bar.
2 Double-click the Cleaners icon in the Definitions group.

► To view cleaner definitions

1 Click the ID tab.
2 Select a cleaner from the list to display the information on the right.
3 Click Close.

Tips

- You cannot change cleaner details.
- “Used on tests” gives a list of the tests using this particular cleaner.
- You can assign permanent rack positions to cleaners in Configuration / Lab / Reserve Positions, or assign temporary placements using the Place Samples dialog box. Cleaners can also be identified by barcode.

► To view the cleaner history

1 Click the History tab.
2 Select a cleaner from the list to display the information on the right.
3 Click Close.

About diluent definitions

Diluent definitions are automatically installed with the associated test.

You can use the Configuration Diluent dialog box to view existing definitions, the dilution history, and to load a new diluent definition.

► To use the Configuration Diluent Definitions dialog box:

1 Click Configuration on the navigation bar.
2 Double-click the Diluents icon in the Definitions group.

► To view diluent definitions

1 Click the ID tab.
2 Select a diluent from the list to display the information on the right.
3 Click Close.

Tips

- You cannot change diluent details.
- You can assign permanent rack positions to diluents in Configuration / Lab / Reserve Positions, or assign temporary placements using the Place Samples dialog box. Diluents can also be identified by barcode.

Loading test application software

Test application software (TAS), such as test, calibration, control, or diluent definitions are are either delivered on diskettes, or as file, which can be loaded to a USB Memory Stick.

You can conveniently load TAS information by using the Load TAS Diskette function.

Overview

Loading TAS files is performed in two phases:

In a first step, your existing TAS files are copied to a backup directory on your hard disk. This directory is created automatically if it does not exist. (Default name: C:\Roche\Instrument\TAS\backup).

Next, the new compressed TAS files are copied to your hard disk and automatically expanded.

Both in the backup and in the TAS directory, existing files with identical file names are overwritten. No files are deleted.

Precondition

You need user access level 6.

- *TAS files (Test Application Software files) are usually sent as .zip files.*
- *TAS files are always named "pbxx-xxx ickvxxxxvx".*
- *The following procedure to load a TAS via USB Memory Stick uses the TAS 35.19v2 as example.*

► To load a TAS via USB Memory Stick

1 Save the zip-file "pb11-022 ickv3519v2 end.zip" to the hard disk of a computer.

2 Double-click the saved zip-file to show its content.

3 Copy the file „ickv3519v2.exe" to a USB Memory Stick.

4 Switch the *Cedex Bio HT* analyzer to Standby mode.

5 Connect the USB Memory Stick to the USB port of the computer of the *Cedex Bio HT* analyzer.

6 Press "Windows key" + E on the keyboard of the computer of the *Cedex Bio HT* analyzer to open the Windows Explorer.

7 Click the USB Memory Stick to display its content.

8 Copy the file "ickv3519v2.exe".

9 Change directory to C:\Roche\Instrument\TAS in the open Windows Explorer.

10 Insert the file "ickv3519v2.exe" into this folder.

11 Double-click the file "ickv3519v2.exe".

The WinZip SelfExtractor dialog box is displayed.

12 Click Extract to continue.

The message "557 file(s) successfully extracted" is displayed.

13 Click OK.

14 Click Close to close the WinZip SelfExtractor.

15 Click the X in the top right corner to close the Windows Explorer.

► To load a TAS via diskette

1 Choose Tools > Load TAS Diskette from any work area.

The first Load TAS Diskette dialog box is displayed.

2 Insert the TAS diskette in the internal or external drive.

3 Click Yes to continue.

The second Load TAS Diskette dialog box is displayed.

4 On the second Load TAS Diskette dialog box

- Select the a:\ drive from the Drives list.
- Select TAS Files (ick*.EXE) from the List files of type list.
- Select the appropriate file name in the File name list.
- Click OK.

When the copying process is completed a confirmation dialog box is displayed.

5 Remove the diskette from the drive.

6 Click OK.

Archiving and reloading definitions

It is important to archive definitions regularly so that, in the unlikely event of a system failure, the archived definitions can be used to reload the system setup quickly and safely.

► To archive definitions and system parameters

1 In the Configuration work area, choose File > Archive Definitions from the menu bar, or click 💾 on the toolbar.

The Archive Definitions dialog box is displayed.

2 Select one set of definitions from the list.

3 Click OK.

The corresponding Archive dialog box is displayed.

4 Select the item(s) to be archived.

5 Click Archive.

The Archive Destination dialog box is displayed.

6 Specify the path for the location of the archive.

7 Click OK.

8 The Archive in progress dialog is displayed where you may be prompted to confirm the action.

Tips

- You can archive only one set of definitions at a time.
- Always archive data to drive F.
- You must have read/write permission for each set of items you wish to archive.

👁 *"Archiving system information" on page B-63*

► To load definitions and system parameters from the archive

1 In the Configuration work area, choose File > Load Definitions from the menu bar or click 💾 on the toolbar.

The Load Definitions dialog box is displayed.

2 Select the definition to be loaded.

3 Click OK.

4 Specify the path name of the archive from where the definitions are to be loaded.

5 Click OK.

6 Select the item to be loaded.

7 Click Load.

8 Click Cancel to complete the process.

System group

Generally, the system group is used to modify *Cedex Bio HT* system settings that have been loaded during the installation process by Roche Service personnel. You can subsequently modify settings using the dialogs in the System group. You can make modifications only if you have the appropriate user access level.

The procedures for defining new users and user access levels are described here.

Use the System group to configure general system settings and database setup. You can also specify tubes and racks, define how results are handled and modify processing options.

General Click the General icon to configure general details including user access and levels, host interface, system details, barcode specification, ISE settings.

Database Click the Database icon to configure the database for automatic actions, order demographics, result comments, and activation of QC rules.

Lab Click the Lab icon to specify sample tubes and types, assign tubes to racks, and define racks for calibrators, controls, diluents, and ISE solutions.

Result Handling Click the Result Handling icon to specify how flagged and unflagged results are automatically handled for samples, controls, calibrations, and calculated results.

Processing Click the Processing icon to specify processing options for report layouts, results uploaded to the host, the test processing sequence, and extra wash cycles for specific tests.

User access

You use the Configuration General dialog box to add new users, modify user details and define user access levels.

► **To use the Configuration General dialog box:**

1. Click Configuration on the navigation bar.
2. Double-click the General icon in the System group.

Assigning and deleting user details

► **To assign a user level to a user**

1. Click General
2. Click the User Access tab.
3. Click Add. A new information box is displayed indicated by an arrow.
4. Type the user name, level, user ID, and password.
5. Click OK.

Tips

- User name is up to 16 alphanumeric characters.
- Levels are 1 (lowest) to 6 (highest); 1 is the default.

- User ID is up to six alphanumeric characters and must be unique.
- Password is up to six alphanumeric characters. The password is case-sensitive.

► To delete a user

1. Double-click General
2. Click the User Access tab.
3. Select the required user and click Delete.
4. Click OK to confirm the new settings and close the dialog box.

Assigning user levels to functions

► To assign user levels

1. Click the User Level tab.
2. Select the user levels to be assigned to each function by clicking in the appropriate check boxes. Selecting a function for a specific level automatically selects this function for all higher levels.
3. Click OK to accept the new settings and close the dialog box.

Tips

- Click Default to return all the settings to the original pattern set by Roche.
- There are six definable user levels that govern functionality for menus, buttons, and modifiable data. Generally, users with high user levels will find greater flexibility in using the system with more buttons, menus, and boxes enabled.

Windows group

Use the Windows group to configure or reset the following standard Windows features:

Keyboard Double-click the Keyboard icon to review or modify the layout, language, and other keyboard settings.

Mouse Double-click the Mouse icon to review or modify the buttons, speed, and other settings for the mouse.

Printers Double-click the Printers icon to review or modify the choice of printer and printer settings.

Contact Roche Service before you install a new printer.

Regional Settings Double-click the Regional Settings icon to review or modify:

- regional settings
- number formats
- date and time style
- keyboard settings

Tips

- When defining the number formats, use a period (".") as the Decimal symbol, and make sure the Digit grouping symbol is *not* a period.
- When defining the date formats, Roche recommends using the dd.mm.yyyy or mm/dd/yyyy format. Make sure to use four digits for the year to avoid complications.

Sounds Double-click the Sounds icon to review or modify the types, schemes, and events of sounds.

Appendix H

This appendix gives graphical overviews of the way in which the menus of the work areas and the fluid system are structured. Comprehensive technical specifications and a list of the most commonly used keyboard shortcuts are also included.

Appendix

Supplementary information about the Cedex Bio HT analyzer

This appendix summarizes the technical aspects of the system and gives an overview on the keyboard shortcuts and the structure of the work area menus.

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Technical specifications

These specifications are subject to change without notice.

Physical dimensions

• Tabletop instrument	Width: 135 cm (53.1 in) Height: 75 cm (29.5 in) Height with open lid: 108 cm (42 in) Depth: 66 cm (26 in) Weight: 210 kg (465 lb)
• Printer paper format	A4 (210 mm x 297 mm) US (8.5 in x 11 in)

Power requirements instrument

• Line voltage	100 - 125 V / 200 - 240 V; +10%, -15%
• Line frequency	50 or 60 Hz ±5%
• Current	4 A (230 V) or 8 A (115 V) (typical values, single phase)
• Power consumption	Typical value 700 VA
• Thermal load	2400 BTU/h (2520 kJoules/h)
• Insulation Coordination	Installation category II (IEC 61010-1)

Power requirements computer

• Line voltage	100 - 127 V 200 - 240 V
• Line frequency	50 / 60 Hz
• Current	2.7 A (220 V) or 5.4 A (115 V) (typical values, single phase)
• Power consumption	200 VA
• Thermal load	680 BTU/h (720 kJoules/h)

Laser sources (barcode scanner)

• IEC	Class 2 Laser Product in conformity to IEC 60825-1:2007 Max. output 1.1 mW, Pulse duration: 132 µs Emitted Wavelength: 650 nm
• USA	Complies with 21 CFR 1040.10 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007

Environmental conditions

• Ambient room temperature	15 - 32 °C (59 - 89 °F)
• Relative humidity (in operation)	Maximum 80% at 32 °C (89 °F) Minimum 30%
• Maximum altitude	2000 m (6500 feet)
• Pollution	Degree 2 (IEC 61010-1)

Water requirements

• Purity	Laboratory Reagent Grade, type I NCCLS, bidistilled or deionized water: >0.6MΩcm or <1.5µS/cm <0.05 Silicate (mg/L, as SiO_2) Maximum microbiologic content of 10 colony forming units/mL. Particulate matter (>0.2 µm) <500/L. Organic compound via activated carbon treatment.
• Supply	From external reservoir or via direct connection to deionized water supply (optional).
• Usage/Drainage	Approximately 2 L/h (0.53 US gallon/h) in operating mode
• Minimum flow rate	0.2 L/min (0.053 US gallon/min)

Plumbing requirements

• Connection	Optional direct connection to deionized water supply.
• Fluid waste disposal	Fluid waste disposal via direct connection to sanitary sewer system.

Waste handling

- Cuvettes with samples and reagents are disposed into an enclosed container inside the instrument. The container can be removed and disposed of by the user.

Warning

Liquid waste
Danger of infectious waste material. This can cause severe illness. Avoid direct contact with waste.
The pH of the liquid waste varies between pH 3 and 5, depending on the assays and the sequence of the assays run. Liquid waste must be treated as potentially infectious material.

For additional information on hazardous substances, refer to the instruction for use of respective reagent kit used on the relevant instrument.

System principle

- Random and continuous access, sample selective instrument
- Integration of four measuring principles with capacity of up to 36 tests on board
- Separate instrument and data station

Measurement principles

• Absorbance photometry	Enzymes, substrates, chemicals
• Fluorescence polarimetry	Hormones, special substances
• Turbidimetry	Specific proteins
• Potentiometry	Na^+, K^+, Cl^-, Li^+

Throughput

- Up to 400 tests per hour
- Up to 260 tests per hour consolidated

Urgent analyses (STAT interrupt)

- STAT samples prioritized and performed immediately

Samples

• Sample tubes and cups	Primary or secondary tubes: 16 x 100 mm, 13 x 100 mm, 16 x 75 mm, 13 x 75 mm Cups: Eppendorf cup 1.5 mL Cup on tube: Micro Cups 0.5 mL or Sample Cups 1.5 mL on Adapter Cups or on primary or secondary tubes 16 x 100 mm, 16 x 75 mm.
• Sample volumes	Typically 2 - 10 µL per test ISE: 20 µL (indirect mode) 97 µL (direct mode)
• Sample types	Aqueous solutions free of solids
• Sample loading capacity	Up to 90 samples on board
• Sample handling	Rack system for samples, calibrators and controls Up to six racks of 15 sample tubes on board LED icons indicating rack status Automatic predilution Postdilution and postconcentration with user-definable factors Offline dilution factors can be entered
• Sample barcode	Positive sample identification by barcode scanner. Codabar 2 of 7, Code 39, Interleaved 2 of 5, Code 128

Calibration

• Linear and nonlinear	Multiple standards with single- and two-point correction. Automatic dilution of multipoint standard curves.
• Stability	Typically: Each lot for enzymes, substrates, or serum proteins.

Reagent cassettes

• Test capacity	Test dependent. Standardized cassettes for all tests.
• Cassette identification	Automatic barcode reading; each cassette uniquely coded for inventory control.
• On-board storage capacity	32 cassettes
• Cassette storage temperature	10 - 15 °C (50-59 °F)
• On-board stability	Test dependent, typically 4 - 12 weeks.

Cuvettes

• Reaction volume	120 - 245 µL
• Path length	5 mm
• Composition	PMMA acrylic plastic
• Cuvette reservoir capacity	1000 disposable cuvettes, refilling possible during operation
• Waste container capacity	1000 cuvettes

Photometry analyzer

• Cuvette capacity	71 cuvettes with automatic loading/unloading
• System cycle time	10.6 seconds
• Temperature control	Heated air bath 37 °C (99 °F)

Absorbance module

• Spectrophotometer	Grating monochromator and diode array
• Light source	Halogen lamp, 100 W
• Wavelength range	340 - 800 nm, 12 wavelengths Mono- and bichromatic measurement
• Measuring range	0 - 2.0 A (for 5 mm path length)

FP photometer

• Measuring principle	Fluorescence polarization
• Light source	Light emitting diode (LED)
• Measuring procedure	2 seconds parallel 2 seconds perpendicular
• Measuring range	0 - 500 mP
• Excitation wavelength	485 nm
• Emission wavelength	515 nm

ISE module

• Measuring principle	Potentiometry
• Measuring method	Direct Indirect
• Measuring cycle	53 seconds
• Calibration interval	One-point calibration every sample measurement. Main calibration every 5 hours.
• Electrode life span	Reference: 2 years Na$^+$: 6 months K$^+$: 6 months Cl$^-$: Labeled orange: 3 months Cl$^-$: Labeled purple: 14 days or 2000 counts Li$^+$: 4 months
• Measuring range	Na$^+$: 20 - 250 mmol/L K$^+$: 0.2 - 30 mmol/L Cl$^-$: 20 - 250 mmol/L Li$^+$: 0.1 - 4 mmol/L

Pipetting system

• Type	XYZ robotic syringe
• Automatic cleaning	All probe tips
• Clot detection	Pressure sensor
• Reproducibility	Sample/ reagent CV <1,5%
• Level detection	Sample level Reagent level: initial photometric cassette check

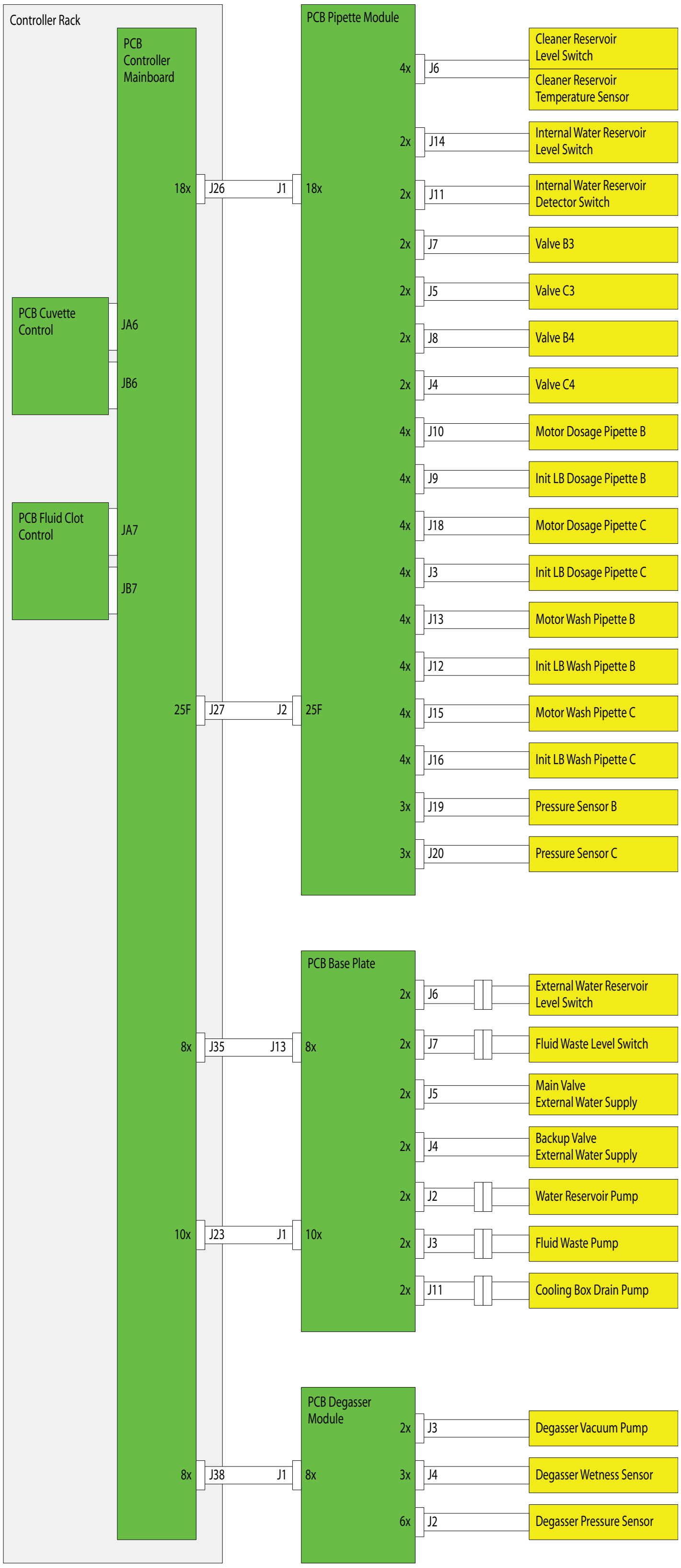
Software and data handling

• Computer	Intel Pentium 800MHz CPU or faster 512 MB RAM or more Hard disk and backup hard disk 3.5 in diskette drive (1.44 MB) (optional external diskette drive with newer models of data station) DVD drive for software updates Integrated network card USB Ports Internal modem (no longer included for data station model rp5800 and later) US keyboard and Mouse (PS2) 19 inch flat screen monitor
• Operating system	Windows XP (English or Japanese)
• Software languages	Default: English Optional: French, German, Italian, Spanish
• Online Help	Context sensitive
• Printer	Standard laser printer (optional)
• Interfaces	Bidirectional RS 232 C interface for host connection; host query mode. Bidirectional RS 232 C interface for Power Ctrl connection. USB 2.0 connector 2nd LAN port for remote service Parallel port (for printer) (no longer included for data station model rp5800 and later).

Safety approvals

CB Test Certificate	IEC 61010-1 (EN-61010-1) International Electrotechnical Commission
c UL us	UL 61010-1 Underwriters Laboratories Inc.
c UL us	CAN/CSA-22.2 No. 61010-1 Canadian Standards Association

Fluid system schematic


Controller Rack
PCB Controller Mainboard
18x
J26
J1
18x
PCB Cuvette Control
JA6
JB6
PCB Fluid Clot Control
JA7
JB7
25F
J27
J2
25F
8x
J35
J13
8x
10x
J23
J1
10x
8x
J38
J1
8x
PCB Pipette Module
4x J6
Cleaner Reservoir Level Switch
Cleaner Reservoir Temperature Sensor
2x J14
Internal Water Reservoir Level Switch
2x J11
Internal Water Reservoir Detector Switch
2x J7
Valve B3
2x J5
Valve C3
2x J8
Valve B4
2x J4
Valve C4
4x J10
Motor Dosage Pipette B
4x J9
Init LB Dosage Pipette B
4x J18
Motor Dosage Pipette C
4x J3
Init LB Dosage Pipette C
4x J13
Motor Wash Pipette B
4x J12
Init LB Wash Pipette B
4x J15
Motor Wash Pipette C
4x J16
Init LB Wash Pipette C
3x J19
Pressure Sensor B
3x J20
Pressure Sensor C
PCB Base Plate
2x J6
External Water Reservoir Level Switch
2x J7
Fluid Waste Level Switch
2x J5
Main Valve External Water Supply
2x J4
Backup Valve External Water Supply
2x J2
Water Reservoir Pump
2x J3
Fluid Waste Pump
2x J11
Cooling Box Drain Pump
PCB Degasser Module
2x J3
Degasser Vacuum Pump
3x J4
Degasser Wetness Sensor
6x J2
Degasser Pressure Sensor

21-03-03 Oe

Keyboard shortcuts

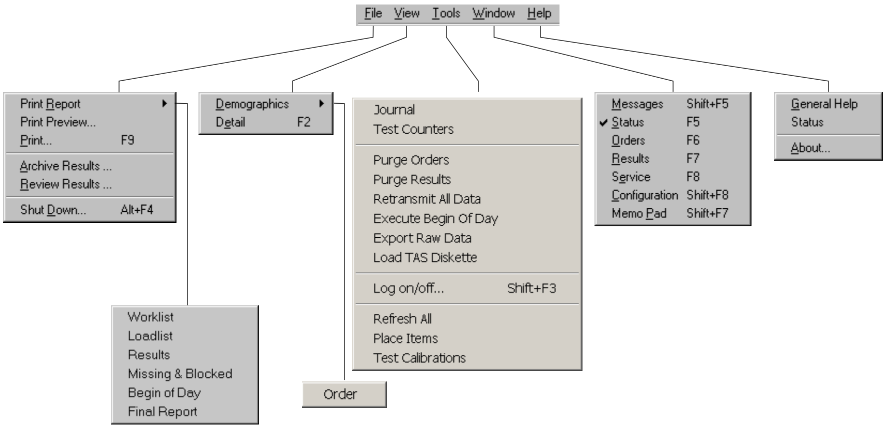
The following *Cedex Bio HT* keyboard shortcuts are available:

F1	Display Help for tab page or dialog box
F3	Find
F5	Status work area
F6	Orders work area
F7	Results work area
F8	Service work area
F9	Print
F10	Select menu bar
F11	Start
F12	Stop
Ctrl + A	Select All (Edit menu)
Ctrl + C	Copy (Edit menu)
Ctrl + V	Paste (Edit menu)
Ctrl + X	Cut (Edit menu)
Ctrl + Z	Undo (Edit menu)
Ctrl + Arrow	Flip through dialog box tabs
Shift + F3	Log on or off
Shift + F5	View Messages dialog box
Shift + F7	Memo Pad
Shift + F8	Configuration work area
Esc	Equivalent to clicking the Cancel or Close button in a dialog box
Tab	Move focus to next object
Alt + F4	Shut Down the system (equivalent to File menu > Shut Down)
Alt + Print Screen	Copy the current window, as a bitmap, to the clipboard
Print Screen	Copies the desktop, as a bitmap, to the clipboard

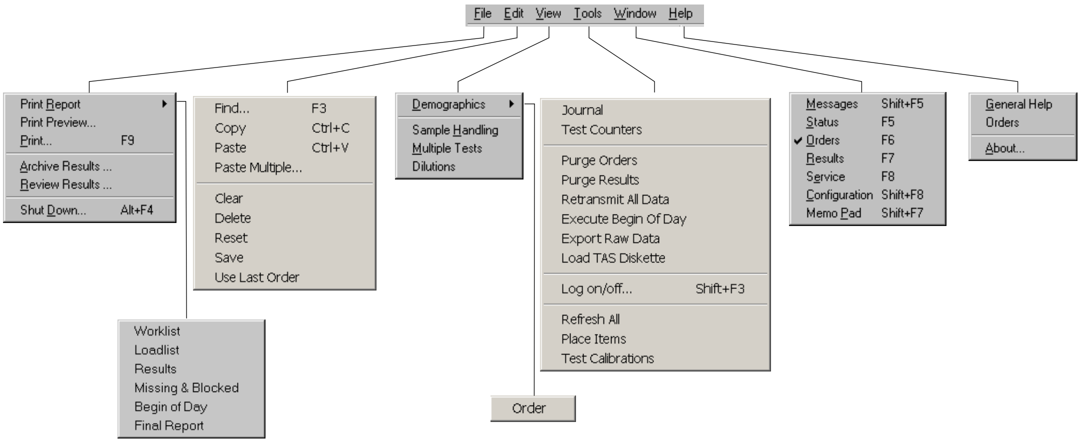
Menu structure

Menu options are context-sensitive, that is, certain options are only available in certain situations. Therefore, some of the options displayed on the following figures may not be available on your system. For reasons of readability, the attempt was made to show as many options in active state as possible.

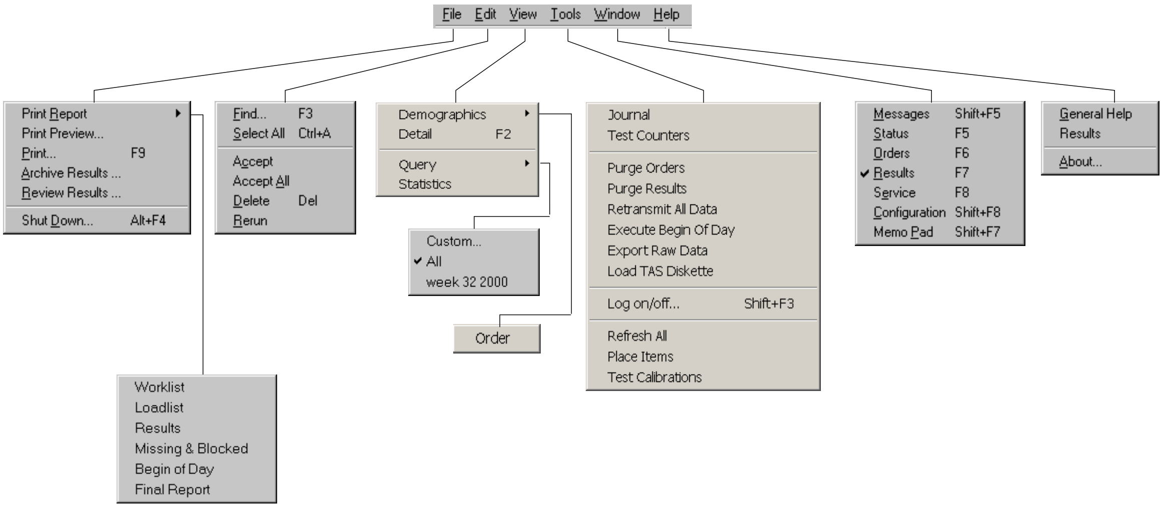
Status menus


File View Tools Window Help
Print Report
Print Preview...
Print... F9
Archive Results ...
Review Results ...
Shut Down... Alt+F4
Worklist
Loadlist
Results
Missing & Blocked
Begin of Day
Final Report
Demographics
Detail F2
Order
Journal
Test Counters
Purge Orders
Purge Results
Retransmit All Data
Execute Begin Of Day
Export Raw Data
Load TAS Diskette
Log on/off... Shift+F3
Refresh All
Place Items
Test Calibrations
Messages Shift+F5
✓ Status F5
Orders F6
Results F7
Service F8
Configuration Shift+F8
Memo Pad Shift+F7
General Help
Status
About...

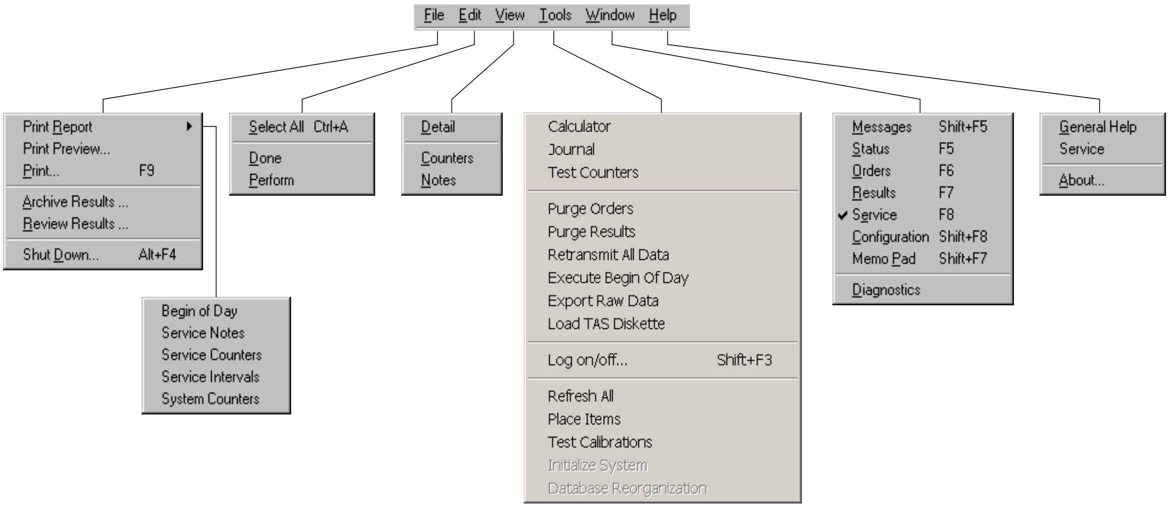
Orders menus


File Edit View Tools Window Help
Print Report
Print Preview...
Print... F9
Archive Results ...
Review Results ...
Shut Down... Alt+F4
Worklist
Loadlist
Results
Missing & Blocked
Begin of Day
Final Report
Find... F3
Copy Ctrl+C
Paste Ctrl+V
Paste Multiple...
Clear
Delete
Reset
Save
Use Last Order
Demographics
Sample Handling
Multiple Tests
Dilutions
Order
Journal
Test Counters
Purge Orders
Purge Results
Retransmit All Data
Execute Begin Of Day
Export Raw Data
Load TAS Diskette
Log on/off... Shift+F3
Refresh All
Place Items
Test Calibrations
Messages Shift+F5
Status F5
✓ Orders F6
Results F7
Service F8
Configuration Shift+F8
Memo Pad Shift+F7
General Help
Orders
About...

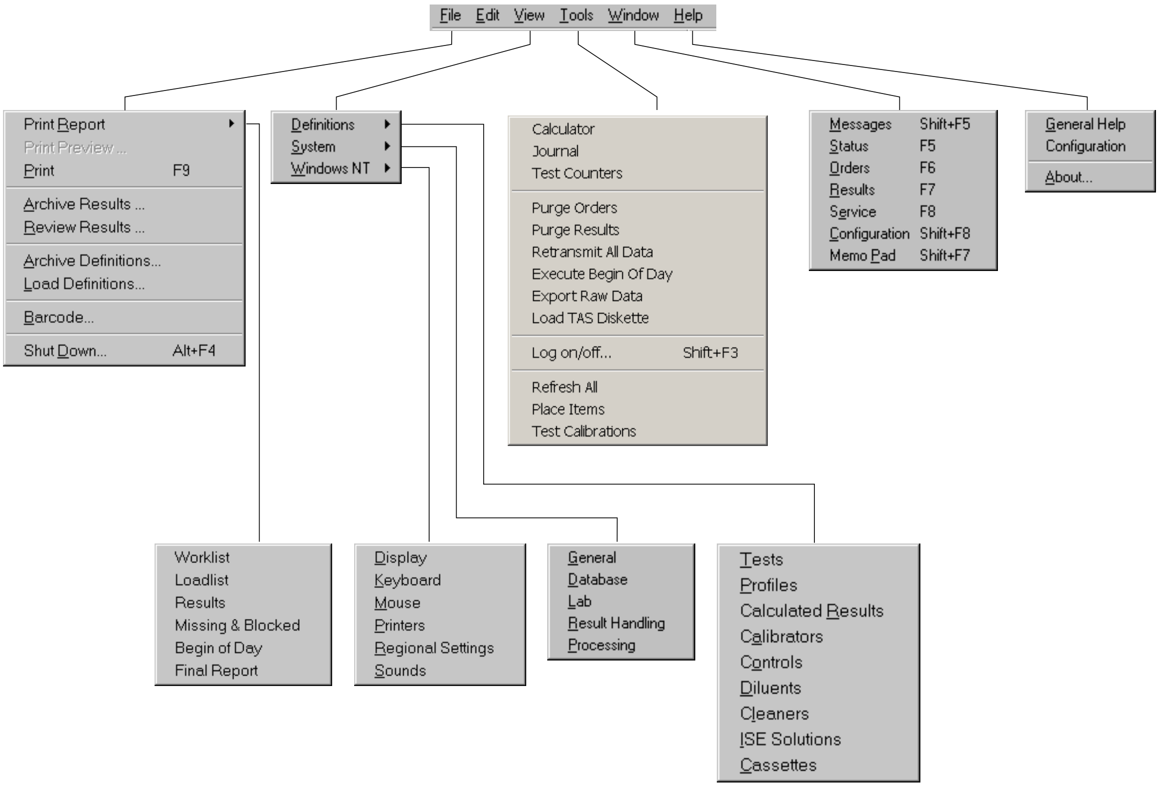
Results menus


File Edit View Tools Window Help
Print Report
Print Preview...
Print... F9
Archive Results ...
Review Results ...
Shut Down... Alt+F4
Worklist
Loadlist
Results
Missing & Blocked
Begin of Day
Final Report
Find... F3
Select All Ctrl+A
Accept
Accept All
Delete Del
Rerun
Demographics
Detail F2
Query
Statistics
Custom...
✓ All
week 32 2000
Order
Journal
Test Counters
Purge Orders
Purge Results
Retransmit All Data
Execute Begin Of Day
Export Raw Data
Load TAS Diskette
Log on/off... Shift+F3
Refresh All
Place Items
Test Calibrations
Messages Shift+F5
Status F5
Orders F6
✓ Results F7
Service F8
Configuration Shift+F8
Memo Pad Shift+F7
General Help
Results
About...

Service menus


File Edit View Tools Window Help
Print Report
Print Preview...
Print... F9
Archive Results ...
Review Results ...
Shut Down... Alt+F4
Begin of Day
Service Notes
Service Counters
Service Intervals
System Counters
Select All Ctrl+A
Done
Perform
Detail
Counters
Notes
Calculator
Journal
Test Counters
Purge Orders
Purge Results
Retransmit All Data
Execute Begin Of Day
Export Raw Data
Load TAS Diskette
Log on/off... Shift+F3
Refresh All
Place Items
Test Calibrations
Initialize System
Database Reorganization
Messages Shift+F5
Status F5
Orders F6
Results F7
✓ Service F8
Configuration Shift+F8
Memo Pad Shift+F7
Diagnostics
General Help
Service
About...

Configuration menus


File Edit View Tools Window Help
Print Report
Print Preview ...
Print F9
Archive Results ...
Review Results ...
Archive Definitions...
Load Definitions...
Barcode...
Shut Down... Alt+F4
Definitions
System
Windows NT
Calculator
Journal
Test Counters
Purge Orders
Purge Results
Retransmit All Data
Execute Begin Of Day
Export Raw Data
Load TAS Diskette
Log on/off... Shift+F3
Refresh All
Place Items
Test Calibrations
Messages Shift+F5
Status F5
Orders F6
Results F7
Service F8
Configuration Shift+F8
Memo Pad Shift+F7
General Help
Configuration
About...
Worklist
Loadlist
Results
Missing & Blocked
Begin of Day
Final Report
Display
Keyboard
Mouse
Printers
Regional Settings
Sounds
General
Database
Lab
Result Handling
Processing
Tests
Profiles
Calculated Results
Calibrators
Controls
Diluents
Cleaners
ISE Solutions
Cassettes

Glossary and Index

I

Glossary

A

Absorbance Photometer Device used to make absorbance photometry measurements. It consists of a halogen light source, optical groupings, monochromator (diffraction grating), preamplifier, filters and diode array. (*See Absorbance Photometry*)

Absorbance Photometry A measurement technique for determining concentrations of substances in body fluids. Substances, or substances bound to reagents absorb specific wavelengths of light. The amount of absorbance is used to calculate the concentration in a solution.

Accept The accept function is used to validate results manually or automatically.

Accuracy Control Is run to detect systematic result errors. (*See also Precontrol, Precision Control, and Quality Control*)

Activate Electrodes ISE service action used to activate electrode surfaces so that the correct potentials are measured.

Activator Activator for *Cedex Bio HT* systems is used to coat ISE electrodes, tubing and sample probes after cleaning procedures.

Analyte The constituent in the sample that is to be determined.

Analyzer *See Photometry analyzer*

Analyzer Rotor Disk that holds cuvettes, temperates them and carries them to the appropriate workstations.

Antigen Excess Check This check detects samples having excess antigen and thus avoids underestimation of the analyte.

Archive Storage of data on samples, orders, and results in Results work area.

Assigned Mean The mean of an analyte in a control material or sample pool assigned by the user in order to establish a precision control.

Assigned Standard Deviation Deviation determined for a sample during precontrol and assigned for use of materials as precision controls.

Assigned Value The assigned value reflects the quantity or activity of an analyte contained in an accuracy control sample. This value is established by the control manufacturer and is supplied with the package insert. The assigned values of Roche controls can be entered with a barcode pen.

Auto Start Automatic instrument start function. Instrument measurements start automatically following order entry or sample rack insertion.

B

Backup Saving of data onto supplementary storage media (disks, tape, etc.). If such data is again required, but no longer available from main storage (hard disk), it can be restored (*see Restore*) from a backup copy.

Barcode An alphanumeric code used to identify a newly loaded cassette, identify samples, and read in calibration and control lot data from the package inserts.

Barcode Pen A device used to read barcodes on package inserts of calibrators and controls.

Barcode Scanner A device which reads barcodes on tubes, racks, and reagent cassettes using a rotating mirror to scan a laser beam across the barcode. A sensor detects the dark and light reflections from the barcode, changing them into electrical pulses which are interpreted by software.

Begin of Day (BOD) The time when the instrument starts its Begin of Day Action (*see Begin of Day Action*). This time can be specified in the Configuration work area.

Begin of Day Action The *Cedex Bio HT* software enables the user to define a specific time as the Begin of Day (for example 6:00 a.m.). At this time the system automatically carries out service actions and other procedures.

Begin of Day Report A report that is automatically generated after the Begin of Day. The report lists service actions that have failed.

Bottle A glass or plastic container having a lid and used for liquids. Some bottles may be used directly on systems. Others have to be used on specific racks (e.g. ISE rack).

C

Calculated Result (Ratio) Result calculated on the basis of two to four test results from the same sample.

Calibration The procedure to standardize each application with material of known concentration. Calibration establishes calibration curve parameters. (*See Calibration Curve Parameter*)

Calibration Curve A plot of known concentrations of calibrators against their signals established during calibration.

Calibration Curve Parameters A series of factors or constants used to mathematically describe the characteristics of a calibration curve. The calibration curve parameters are used to calculate enzyme activity or analyte concentration based on the measured rate values. *Cedex Bio HT* curve parameters are labelled R_0, K_c, A, B, etc.

Calibration Mode A mathematical model to describe the relation between a signal and a concentration in the calibration curve (see Calibration Curve).

Calibrator Solutions with known amounts of added analytes. They are used in different concentrations to adjust a measurement procedure.

Carry-over The phenomenon by which part of an analyte or reagent of a previous pipetting is inadvertently present in the current analysis.

Cassette Area The cooled area where cassettes are loaded into the instrument.

Cassette Number A unique number that identifies a particular cassette.

Cleaner The solution used to wash the interior and exterior of probes to prevent carry-over.

Clot Detection Detects clots during aspiration and dispensing of samples, during washing of probes, or when initializing the system. When a clot is detected a message is displayed.

Coefficient of Variation (CV) Statistical measurement used to evaluate imprecision. Ratio of the standard deviation to the mean of a set of replicate measurements (CV% = SD x 100/mean).

Consumables All materials used during operation that must be replaced regularly. These include cuvettes, cleaner, water, calibrators, controls, cassettes, ISE solutions, etc.

Control (QC) Material used to check accuracy and precision of a system.

Cup A small container used for pediatric samples as well as for calibrator and control material. Preferred vessel if only small amount of fluid is available. Only specific cups can be used on the instrument.

Cup on Tube A dead volume optimized configuration of samples having limited fluid quantities. The fluid can be transferred into a smaller cup that is placed onto a primary tube using the original barcode data of that tube.

Cuvette Disposable plastic containers into which sample, reagents, diluent, and water is pipetted, where the reaction and sample predilution takes place.

D

Daily Start-up Procedures which ensure optimum working conditions such as checking/ loading calibrators and controls, emptying the waste container, or replacing depleted reagents. Daily Start-up includes the Begin of Day (BOD) actions (*see Begin of Day Action*).

Data Station Part of the *Cedex Bio HT* system consisting of computer, monitor and optionally a printer.

Dead Volume Volume remaining in a cup or tube after the last correct pipetting of maximum possible sample pipetting volume.

Degasser A module that removes gas bubbles from the fluid system and helps to improve both accuracy and precision in systems where dissolved gases cause problems.

Demographics Information about an order.

Determination The process of quantifying the concentration of analytes.

Deviation Difference between the assigned value and an actual value of a control sample.

Diluent A liquid used to dilute samples (for example physiological salt solution) or to affect an analytical reaction.

Direct Mode (ISE) ISE measurements made on an undiluted sample.

F

Flag Generated by software, printed with results and also displayed with individual results in the Results work areas. Indicates that the limit of an internal check was exceeded or not reached.

Fluid System Consists of all tubing, pumps, valves, filters, and other devices that support sample, reagent, diluent, and cleaner dispensing.

Fluorescence Polarization (FP) A measurement method where a sample is irradiated with light of a specified (excitation) wavelength. Fluorophores in the reaction mixture (for example fluorescein-labelled reagents) emit light at a second wavelength (fluorescence) and the emitted light is detected at 90 to the excitation beam. A filter mechanism is used to determine the parallel and perpendicular components (polarization) of the emitted light, and thus the concentration of the analyte in the sample.

FP Photometer Device used to make Fluorescence Polarization measurements. It consists of a blue LED light source *(See Light Emitting Diode)*, optics, shutter, dc motor driving a two-position polarization filter, photomultiplier (light amplification) tube and associated high voltage electronics. *(See Fluorescence Polarization)*

Function Keys Keys (F1 to F12) along the top of the keyboard used to enter specific commands.

G

Grid *See Tube Height Adapter*

H

Host Computer External computer of the customer's Laboratory Information System communicating with the *Cedex Bio HT* instrument. Allows rapid processing of the large quantities of data generated. Communication between the Host and the *Cedex Bio HT* analyzer is provided by the Cedex Bio HT Host Interface. *(See Host Interface)*

Host Interface Hardware and software allowing bidirectional communication between the *Cedex Bio HT* data station and the Host Computer. The hardware is an RS-232 serial interface. *(See Host Computer)*

I

Identification Number (ID) Number used to uniquely identify samples, cassettes, tests, calibrators, controls, and diluents.

Indirect Mode (ISE) ISE measurements made on a diluted sample.

Initialization Status while the system performs any kind of initialization (e.g. of the fluid system or the transfer arms) - after power up or before being operative.

Integrated cassette volume check This function checks the reagent filling of each cassette. It ensures that the system correctly aspirates the number of tests the cassette is specified for.

ISE Ion-selective electrode.

ISE Module The ISE module is an electro-mechanical device used to determine ionic concentrations in undiluted and diluted samples using electrodes selective to different ions. The ISE module is one of the two measurement areas of the instrument, the Photometry Analyzer being the other.

ISE Rack Contains most of the fluids (Activator, ISE Solutions 1, 2, 3, ISE Deproteinizer, ISE Etcher) needed to measure the ionic concentrations in a sample and to maintain the electrodes. Diluents necessary for other tests can also be placed on the ISE rack.

J

Journal A list of all recent results and messages generated by the instrument. This list can be accessed through the software.

L

Level Detection The automatic determination of the level of fluid by the probes. Level detection establishes whether there is enough fluid to perform the incipient pipetting operation.

Light Emitting Diode (LED) Solid state lamp available in different colors. For the *Cedex Bio HT* analyzer, LEDs are used for the warning light and rack status indicators on the front of the instrument, the fuse indicators, the FP photometer, etc.

Log Off Quit access to the system - no current user is recorded.

Log On Gain access to the system by entering a user name and, if required, a password. The given user name is taken as current user and may be printed on records.

Lot Consumables produced from the same materials in the same production run and subjected to the same quality control procedures.

M

Memo Pad Electronic note pad used to leave messages or supplementary information for the next user.

Message Message icons on the user interface informing the user that intervention is required. An alarm sounds when an urgent message appears.

N

Navigation bar The column of buttons used for quick access to the work areas.

O

Online Help System in which the user can call up information in a context-sensitive manner and search for any given term. Just click the Help button or press F1 to access Online Help.

Operating Status while the system is performing pipetting, measurement, and calculation activities.

Order An entry in the Orders work area to run a sample measurement.

Order Demographics Customizable information for orders.

Order ID Unique identifier for an order. Can only be used once on a given day. The sample order identification refers to a number of sample tubes (one or more specimen types) of a given sample collected for a panel of different tests.

P

Password Log on identification allowing user access to the *Cedex Bio HT* software.

Permissible Deviation The maximum acceptable deviation of the control results from the assigned value of the accuracy controls.

Photometry Analyzer Consists of workstations, the rotor, the Fluorescence Polarization (FP) Photometer and the Absorbance (ABS) Photometer.

Postaction Definable pipetting action that can be either dilution or concentration. It is triggered by appearance of several flags (e.g. >test range, antigen excess).

Postpone Calibration Overruling of a due calibration by the user. All results of a test with a postponed calibration are flagged.

Power up The instrument is designed to be left switched on. For maintenance or long breaks the system may have to be switched off (shutdown) and on (power up) again.

Precision Control Precision controls are run to detect random errors (*see also Accuracy Control, Precontrol, and Quality Control*).

Precontrol Before a control material can be included as a precision control (*see Precision Control*), it should be tested along with the samples. The results from the precontrol period, the assigned mean, and the standard deviation are used to automatically establish a precision control.

Primary Wavelength Main wavelength for signal detection in bichromatic (ABS) measurements. *(See Absorbance Photometry)*

Profile Set of tests frequently ordered in combination.

Purge Command to clear all completed orders and results from the work areas.

Q

Quality Control (QC) A tool which verifies accuracy and precision of results. *Cedex Bio HT* quality control encompasses the functions of accuracy control, precision control, limit control, and precontrol.

Quality Control Rules A set of statistical rules that help to identify problems with the instrument.

Query Command to find and display the entries in the work areas according to customized search criteria.

R

Rack Carrier holding containers used on specific systems.

Rack Number A number that identifies a particular rack. This number is assigned when the rack is defined to the system.

Rack Status Display Consists of a set of lights that show the status of the racks. The icon on each light indicates the type of rack. The color and whether the light is flashing or steady indicates the rack status.

Random Access Analysis Ability to run analyses flexibly in any order, as opposed to in batches.

Rate Absorbance difference between first and last measurement cycle (ΔA) or change in absorbance per minute (ΔA/min).

Ratio *See Calculated Result*

Reference Wavelength Second wavelength in bichromatic (ABS) measurements which corrects for interfering constituents in the sample. *(See Absorbance Photometry)*

Repeat Command to perform a test, calibration, or control order as in the original run.

Replicates Multiple repeated measurements of the same sample, calibrator, or control.

Report A collated set of data related to the running of the instrument (for example test results, resource requirements, or service actions performed). Reports are automatically generated and printed on request.

Rerun Command to perform the same test with a concentrated or diluted sample either by decreasing the diluent or by increasing the sample volume.

Restore Command to reload data from an external storage medium to the data station hard disk. (*See Backup*)

Rotor *See Analyzer Rotor*

S

Sample Area The area on the instrument where sample racks and the ISE rack are located.

Sample Cup *See Cup*

Sample Tube *See Tube*

Scroll Bars Thin rectangles normally found along the right side and bottom of windows. The bars have arrows at each end and a single rectangular box in them. Clicking on the arrows moves the contents of the window in the same direction. The box of the scroll bar can be moved with the mouse to provide the same effect as clicking on the arrows.

Service Action A service procedure that must be performed to keep the instrument running correctly.

Shutdown Command to switch off the software and instrument for longer breaks or if severe errors occur.

Sleeping Status while the system is in energy conservation mode.

Standard Deviation (SD) The square root of the average of the squares of the deviations from the mean.

Standby Status when the system does not perform any measurement activities - but only a limited initialization / preparation time is required.

STAT Abbreviation for Short Turnaround Time. Emergency order automatically given the highest priority.

Status Bar An area at the bottom of the main window where information and the current date and time are displayed.

Stop Button to achieve one of the following:
-Stop pipetting samples but finish processing already scheduled activities without interruption or loss.
-Stop all system operations immediately. The system aborts all current activities. The system may need special attention before it can resume its normal operation.

T

Test Class A category of related tests which are handled in the same way.

Test Group A set of tests that are displayed in the Orders work area. A test can belong to more than one test group.

Toolbar A bar positioned below the menu bar containing a series of shortcut buttons.

Tube Vessel for samples and Cal/QC/Dil fluids used on all kind of racks within the system. It is a primary vessel and may or may not have a barcode label for positive sample identification. A sample tube contains sample of one specific specimen (sample) type.

Tube Height Adapter (Grid) Device to adjust the height of tubes or cups on aluminum cup adapters.

U

User Access Access allowed to different users of the software. Each level has its own password and its own group of operational permissions.

User Interface Link between the system and the user. The sum of screen displays supported by the *Cedex Bio HT* software.

V

Volume Management An internal software calculation mode. It is based on volume information to find the correct immersion depth of the sample probe if a new bottle is placed on a specific position of the ISE rack. Delivers information in percent about the filling status of bottles.

W

Waste The fluids (samples, cleaning solutions, etc.) and solid materials (cuvettes) discarded by the instrument.

Waste Container The waste container collects used cuvettes and potentially infectious fluids. Both the waste container and contents must be disposed of according to the local legal requirements associated with high level waste.

Work area Main areas of the user interface such as Results and Orders work areas.

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Revisions

J

Use this section of the manual as a repository for updates to the Cedex Bio HT Operator's Manual. You can also use this section to insert your own notes about the system, so that all information about the system is in one place.